HOSPITAL INFORMATION SYSTEMS FOR CLINICAL AND RESEARCH APPLICATIONS: A SURVEY OF THE ISSUES

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> By way of compensation for the loss of a world that pulsed with our blood and breathed with our breath, we have developed an enthusiasm for facts--mountains of facts far beyond any single individual's power to survey. We have the pious hope that this incidental accumulation of facts will form a meaningful whole, but nobody is quite sure, because no human brain can possibly comprehend the gigantic sum total of this mass produced knowledge (97, p.485).

INTRODUCTION

In this age of the information and technology explosion, we collectively share the hope or expectation that the "mountains of facts" alluded to by Carl Jung can be synthesized into a meaningful whole through the power of computer technology. Data--facts--are themselves no more than established or asserted observations, measurements, or premises which alone provide little or nothing by way of insight or understanding (5, 101, 173, 215). Only when facts are properly selected and arranged do they become informative, for information has to do with the utility, meaning, and value of data to a decision-maker. The power and value of information, of course, depend on the accuracy and clarity of its expression or transmission (a technical problem), the precision with which the desired meaning vis-a-vis the decision at hand is conveyed (a semantic problem), and the timeliness and effectiveness of the information with regard to the decision-maker's ultimate action (an effectiveness problem) (125).

The dissemination and utilization of information in a medical system is critical at all levels of decision-making, yet many pivotal decisions are based on fragmentary information of uncertain quality (215, 219). In some cases the rudimentary data simply are not available, but oftentimes decision-makers go thirsty in a veritable sea of uncoordinated information. The information revolution, in contrast to the data explosion, remains conceptually, technologically, and organizationally undeveloped (215).

Comprehensive, high quality health care requires that providers and managers relate all relevant medical knowledge to the needs of individuals in the broadest possible context and in the most coordinated manner possible. Yet the sheer amount of information required is rapidly outdistancing the recall and synthesizing capabilities of most physicians and administrators. Computers are available to help gather, store, process, and organize medical data, but as Ball and Shannon (11) pointed out:

> it should be clear that specialists are no longer turning to technology merely to 'do' things, but also that they are now turning to technology to 'think' things. Unfortunately, the choice of things about which to think is almost limitless, and the massive, complex body of medical knowledge today requires many minds to cope with functions that were carried out by one mind a century ago.

Following the successful implementation of computers in business, computer companies have attempted to introduce their technology into the field of health care. Excessive costs, unsuitable computer configurations, vendors' lack of understanding of medical information, and lack of interest and participation from the community of practicing physicians contributed to the failure of many early projects (224). Nevertheless, hospitals did move into the computer era in the early 1960s, primarily with batch-processing systems developed on an application-by-application basis (7). Although a few hospitals attempted to implement fully integrated systems designed to meet all

hospital information requirements, most were unsuccessful. Some rushed to computerize without adequate planning or a full understanding of system capabilities and limitations. In his final report for a "new generation" of military hospitals in 1971, Arthur Little cautiously recommended against leaping into automation until it could be shown that the promise of computer-based communication systems would be realized and their costs justified (112).

Now more than a decade later, several important advances in computer technology have approached the realization of a total automated hospital information system (HIS). The development of relatively inexpensive minicomputers, the availability of on-line access systems, and the increase in attention and effort given to system integration have all contributed to the interest in hospital information systems. In 1979, the American Hospital Association found that 65% of the responding hospitals reported using computer systems and/or services, and 21% of the remaining respondents indicated that they planned to use computers within the next five years (203). A 1980 GAO report estimated that half of the larger short-term general hospitals will install information systems by the end of the decade (200).

Increased demand for information processing has provided much of the incentive for computer technology development (218). The data explosion and the formalization of large-scale data bases have made computerization essential. Wiederhold, Fries, and Weyl (219) report that it typically takes more than one hour to deliver a standard written record for a given patient and months to collect data to study a disease or treatment modality. McAlister, Covvey, and McAlister (120) found that the average written record is about 50 pages long, and that doctors spend 1-2 hours per day writing these records. Operating constraints such as personnel ceilings and chronic staffing shortages compound the problem and may substantially increase the need for computer support (17). Waters and Murphy (208) have identified nine reasons why the health care industry needs computerized health information systems. Briefly, these are (a) adequate and timely care to patients, (b) research, (c) administrative functions, (d) legal protection, (e) accreditation, (f) financial management, (g) information processing, (h) justification of use of resources, and (i) scheduling of patients, staff, and facilities (207).

Internal and external pressures for accountability represent a growing concern among health care providers. The continued escalation of government report requirements and the growing demand for quality controls upon hospital operations have prompted many hospitals to develop or procure automated information systems to provide the necessary data in a timely and financially acceptable way (95). The medical record, once primarily a worksheet for the physician to jot down personal reminders about a patient, has evolved into a legal document (234). Professional records are used as a legal index of a doctor's professional conduct and can serve in court as a barometer of the standard of care delivered by the physician (153). In many malpractice cases, the court examines a physician's professional judgment and conduct as reflected in his or her medical records. Therefore, records must be much more detailed and explicit than they customarily have been and must indicate not only the diagnosis (or other medical decision) that was reached, but also the means by which it was reached, i.e., the process of rational decision-making (153). Current development efforts in automated medical records represent an attempt to alleviate the physician's growing clerical burden while satisfying the requirements for legal liability.

Legal issues surrounding computers in health care go beyond the forensic use of medical records. Watson (209) speculates that courts may eventually impose liability for a hospital's or a physician's failure to use a computer when its application could have prevented a negative outcome. This means that not only automated records but computer-assisted health care delivery may soon become a standard of acceptable health care delivery. While computerization may help meet these medical-legal concerns, it will create other legal problems. These include the regulation of medical computers, determination of program ownership copyrights, liability for injuries due to product or program design, and contract agreements for computer systems (26).

Computer technology is advancing rapidly in response to these and other medical information processing needs. In fact, computer hardware parameters such as processing speeds and storage capacity no longer pose any serious limitations (107). Software and system development now constitute the limiting factors. The development of workable software packages depends primarily on a careful consideration of the needs and goals of individual users (80). The present report is designed to focus attention of both clinicians and researchers on the salient issues involved in the design and use of an automated medical information system. While current technology provides a variety of means to acquire and manipulate data, potential users must decide what data should be captured and how this process should be performed. Discussions should include a careful examination of the purposes of the desired information system, the technical options available for meeting those purposes, and an evaluation of the performance records of candidate systems in light of the desired ends. The present report is designed to provide a foundation for such discussion. It will review the current state of the art of computer applications in medicine, focusing specifically on clinical applications. It will then examine the usefulness of present data collection efforts and will suggest alternatives based on the information needs of clinicians and researchers. Finally, it will consider the major issues involved in designing, managing, and implementing a computerized hospital information system.

CLINICAL APPLICATIONS

The development of hospital information systems grew out of computer developments in business and industry (68, 156). Partly as a result of this genesis, administrative applications (fiscal management, medical audits, patient scheduling, planning, etc.) are more commonplace and their developmental problems less severe than are clinical applications of patient management (including direct care, provider support, and medical records) and ancillary support (5, 68, 123, 167, 232).

Apart from the greater availability of administrative applications, management is often emphasized because health care is an industry, with goals similar to those of any business: cost containment, productivity improvement, utilization analysis, program planning and evaluation, accounting, payroll, and inventory control (6, 138, 224). As a result, many planners and policy makers in the health care industry believe that the main purpose of a hospital information system is to provide management with the data required to operate efficiently, review and control effectively, and plan sensibly (4, 156). Furthermore, the primary justification for an automated system is usually the cost-saving financial administrative services. It is interesting to note in this regard that one of the largest and most popular commercial systems, COSTAR, began by developing medical

modules and subsequently added financial [illegible] administrative modules in order to achieve acceptance and transfer (104).

However, the primacy of administrative functions is being challenged by many who believe that the main purpose of automated records is to assist practitioners and facilitate clinical decision making (180, 208). These individuals argue that the main impact of a clinical information system on the quality and cost of care is made by the services it provides at the clinical level (123), and that the concern for cost savings with an automated system should be replaced with the original concern for improved medical care and management (32). In his comments summarizing the 1980 Symposium on Computer Applications in Medical Care, Bush (32) expressed concern over the overwhelming trend away from the original medical goals in favor of administrative priorities. He concluded that this trend was contrary to (a) the original goal of HIS developers, (b) the normal principles of management, and (c) the social goals of current law regulating capital expenditures by hospitals.

The problem, of course, is that practitioners and managers have different perceptions of the overall practice. The physician's responsibility is to maintain the health of the patients, while the administrator's objective is to maintain the health of the practice as a business (169). With the advent of computerized data bases, however, it is becoming clear that for many clinical applications of medical information there are corresponding administrative and research uses of the same data.

In order to maintain a manageable focus, this report will primarily address information systems for clinical and research applications. While computer applications in medical research and quality assurance will be considered in later sections, the remainder of this section will provide an overview of many wide-ranging clinical applications of automated hospital information systems. In general, these clinical applications will be discussed in terms of (a) direct care, testing and monitoring, (b) diagnostic and decision-making assistance, (c) management of comprehensive medical records, (d) support of ancillary services, and (e) major evaluation projects.

Direct Care, Testing, and Monitoring

A number of patient observation devices are in various stages of development. For example, a noninvasive, real-time device for pulmonary monitoring which promises to become "the pulmonary equivalent of an ECG" has been developed (2). Its potential applications include monitoring critically ill patients, testing respiratory protective devices, and monitoring ventilation under unusual environmental conditions. A microcomputer that takes a continuous electrocardiogram and can be worn by a patient during his daily activities has been designed to sound a warning and display a message in the event of heartbeat irregularity (107). Intrapartum electronic fetal monitoring has also been computerized to analyze more accurately and interpret fetal heart rate and uterine activity (230).

In addition to these stand-alone devices, computerized databanks and information-guided dialogues have been shown to enhance patient care directly. For example, physician's assistants, with the aid of a computer, are able to manage medication regimens and monitor status changes in diabetic patients (22). The computer utilizes both patient history and new information to make recommendations pertaining to diet and insulin, as well as additional laboratory tests and further

consultations. In this particular example, when the changes in insulin recommended by the computer were evaluated, they were found to agree with those of the physician in almost every instance, and in no case did the computer make a hazardous recommendation. Computers are also being used by patients themselves to manage their own education, evaluation, and counseling (181, 189, 202). The goal of such systems is to promote and facilitate self care.

Diagnostic and Decision-Making Assistance

The innovative and relatively young field of computer-aided medical decision analysis generated considerable antagonism among medical professionals when it was first brought to popular attention in the early 1960s. Many physicians feared that computers would take over medical diagnosis, and that computer-assisted techniques would force a major change in their usual mode of practice. They further contended that the data necessary for applying decision analysis (e.g., probability estimates of diagnosis or surgical risk) were typically unreliable or in dispute, and that decision analysis itself took too much time and was not a practical clinical tool. Although many of these concerns are unwarranted (173), the technique continues to be viewed as a threat and resistance remains among many physicians. Recent developments at the University of Maryland may help overcome the medical community's resistance to decision support. Scientists there are developing a "knowledge management system" (KMS) capable of monitoring and managing multiple medical conditions simultaneously and of reformulating diagnostic hypotheses in light of current medical information (46). It is hoped that the KMS can be refined sufficiently for medically-oriented knowledge bases to be transformed into broadly applicable decision support systems, systems which will transfer easily from one treatment setting to another.

Modern medicine is faced with the challenging situation of having more useful medical knowledge available than can be assimilated by any single physician. Yet that vast knowledge is not necessarily available to any particular physician at any given time. The problem is not that the physician's judgment is inadequate (and therefore must be supplemented or replaced by a computer); it is rather an issue of bringing the physician into convenient contact with relevant information (20, 101).

A possible solution to this logistical problem is the computer-assisted representation of clinical data to the physician. The models developed to accomplish this task are generally of three types: models based on physicians' thought processes, models based on the physiological relationships manifested in the disease state, and statistical relationships. In their review of the research on computer-aided diagnosis, Wardle and Wardle (206) assessed these three models in terms of their accuracy vis-a-vis clinical methods. They found that computers typically improve diagnostic accuracy by about 10%, and they concluded that Bayesian statistical models are best suited to the probabilistic nature of medical data. They noted that these models were in need of improvement and further research, however. Although Lusted's (114) briefer review of medical decision-making studies admonished researchers that "computers can't do diagnosis, and physicians don't think Bayes," he, like Wardle and Wardle, acknowledged the value of computer-assisted decision-making. The point is that while computer technology and mathematical techniques are useful tools for investigating medical problems, it remains the physician's right and responsibility to make decisions and diagnoses based on the results of that investigation.

The merit of a decision-making model depends on its relationship to the health care process and ultimately on its usefulness to the clinician. Three areas in which computers can be useful aids to diagnosis have been cited as (a) the initial state of diagnosis, which identifies a range of diagnostic possibilities, (b) the differential diagnosis, in which the physician selects one or two of the initially identified alternatives, and (c) the direct analysis of test results to crystallize a single differential diagnosis (206). The potentials are great, and some individual applications have already proven to be of benefit for improving health care.

In Japan, for example, the computer is being used to perform trend analysis to aid in establishing the prognosis of patients with acute myocardial infarction (136). At the Regenstrief Institute in Indiana, computerized reminders and suggestions regarding certain simple, medication-related events are reducing physician errors and increasing physician response rate to conditions requiring corrective medical action (43, 121, 122, 124). Navy researchers are developing an on-board computer-based medical support system to assist hospital corpsmen aboard nuclear submarines (65). The main purpose of the project is twofold. First, it is expected to compensate for the corpsman's lack of clinical experience and thus help improve the quality of care. Second, it should result in a decrease in unnecessary evacuations, and thereby reduce risks to the patients, costs to the government, and potentially dangerous compromises in the national defense.

Medical Records

In a recent survey, physicians were asked to identify the most popular professional applications of small computers (147). Medical records ranked third in a list of 25 applications (accounting was second, billing was first). This corroborated an earlier survey in which medical documentation was assigned a lower priority than administrative activities such as billing (174). In a fee-free medical environment, however, the automation of the patient record assumes a higher priority. Clinically oriented functions such as checking and cross-checking new results against old ones, diagnoses against treatments, trends in disease, clinical progress, and outcomes could be significantly enhanced by automating the medical records (43).

A computerized medical record has many advantages over a manual record. These advantages include (229, p. 481):

1. Improved record legibility
2. Simultaneous availability of records in multiple locations
3. Improved intercommunication among members of the health care team
4. Ability to organize the medical content of the record according to the needs of various providers
5. Easy implementation of concurrent quality assurance protocols
6. Support of complex management functions necessary for administration and planning in a health care organization
7. Availability of an extensive database to support clinical research

The existing, traditional medical record is usually described as a "source-oriented" document, with entries organized according to the class of provider (nurse, doctor, laboratory, etc.) and sequenced in the order that they were recorded (107). Designers of automated records are attempting to find a more clinically useful and meaningful method of organization. Of these, the Problem-Oriented Medical Record (POMR) has received the most attention (211). By keying patient data to a

problem list, the record actually directs the process of clinical care as it encourages clinicians to form relationships among the data entries that would tend to go unnoticed in other formats (13?, 208). By systematically collecting and organizing data on each problem in the same order that care is given, the record parallels the care process itself, from presenting problem and diagnostic hypothesis to therapy plans and progress notes (107). The progress notes assume a similar order, which has been assigned the acronym SOAP: Subjective information (patient's and provider's perceptions of current conditions), Objective data (physical exam, lab tests, etc.), Assessment of the patient's condition, and Plans for treatment (107, 208). This method of notekeeping is widely accepted and used by providers in the health care industry.

Initial attempts to automate medical records ran into difficulties. For computerization to occur, data had to be in a form that could be read, interpreted, collapsed into computer language, electronically processed, stored, and retrieved (130). This meant that physicians or aides had to complete lengthy checklists and make do with a format having little or no capacity to handle narrative data. Among the general commercial packages that were first available, most had sharply specified capabilities: patient history <u>or</u> laboratory results <u>or</u> radiology data, for instance. Few had even attempted to integrate these services into a comprehensive medical record system (170).

The POMR was the first format to deal successfully with the problems of automating the traditional medical record. In this system, all clinical data entries are reordered to provide a local and computer-compatible format which is arranged so that branching entries are possible (130). This arrangement has the added advantage of allowing a reviewer to audit the care provided to patients far more easily and with much more clarity than does the source-oriented record (208). The POMR unifies the data to prevent fragmentation of diagnostic and therapeutic information and is, therefore, particularly valuable in a teaching hospital.

With the POMR for a core, a completely electronic POMR was created at the PROMIS (Problem-Oriented Medical Information System) Laboratory in Vermont several years ago. This system couples two major bodies of medical knowledge: knowledge concerning the individual patient, and knowledge concerning populations--of people, bacteria, diseases, surgical procedures, etc. (212). The PROMIS system thus goes beyond the POMR and becomes a computerized decision-making system for comprehensive care.

As in any system, however, there are some disadvantages to the POMR (208). There is almost too much information present, which gives rise to a confidentiality problem. In addition, the volume of information requires copying more pages, which creates a cost problem. The advantages seem to outweigh these drawbacks, however (93). In one study, comparative examinations in 600 periodontal patients showed that the problem-oriented medical record yields a much higher information content than that of a nonstandardized record (76). A particularly glowing report comes from the U.S. Naval Air Station in Brunswick, Maine, where users found that the automated POMR system equaled or surpassed the paper medical record in several respects, including legibility, storage life, and nearly instant availability (170). The confidentiality problem was handled by using passwords that limited access to discrete portions of the file, and costs were comparable to those of a standard paper record system. The system was found to require one-third less time for a physician to dictate notes than time previously spent writing longhand notes. Doctors required only about three hours of

instruction to become adept with the system. Patients were pleased with the decreased waiting times and the more complete care afforded by the system. In addition, clerical tasks were reduced while documentation was improved; utilization review, disease surveillance, peer review, and clinical research were all facilitated.

Because the majority of the health care delivery in this country is on an ambulatory basis, special interest is being paid to the development of automated ambulatory medical record systems (AAMRS). Such systems would address the major data and information processing needs in outpatient settings and would form the core of an expanded system of ambulatory services (e.g., decision support programs and automated ECG management processing) (199). The medical record can include patient history and demographic data, presenting symptoms, physical examination data, diagnosis, laboratory and radiology test results, therapy, and patient progress. Some AAMRSs also have report generation capabilities, and most can perform certain management functions such as registration, scheduling, and accounts receivable.

As recently as 1975, ambulatory medical record systems still required substantial development and evaluation (86). Although formal evaluation is still lacking, a follow-up study in late 1980 revealed a much improved level of objective achievement (104). Several promising systems are operational and are evolving into commercial products. There is now good evidence that the outpatient medical record can be stored, used effectively on a regular basis, and transferred to other settings. Minicomputers have emerged as the leading hardware alternative and are used for nearly every large AAMRS. Kuhn and Wiederhold (104) conclude that there is every indication that the AAMRS can have a significant influence on patient outcome, particularly as a result of research supported by automated record systems.

Ancillary Services

Laboratory. Efforts to computerize clinical laboratories were initially directed toward solving operational and technical problems within the laboratory (e.g., cost control, productivity, error rate) (119) and toward the laboratory's computational needs (such as on-line data acquisition, data conversion, and standardization) (154). These early efforts were necessary and helpful, but they had two major shortcomings. First, they ignored the computer's value and capacity for record keeping, and second, they failed to realize that the primary problem of the clinical laboratory is communication, not computation (154). Once these shortcomings were recognized, developers turned to the problems of information management and utilization.

In order to work effectively, the laboratory must receive clear communications from the physicians and provide information when and where it is needed. Acknowledgments back and forth are also necessary to keep track of orders and results. In addition, the laboratory can and should contribute to the effective utilization of its services and provide backup mechanisms to track orders and results. In response to these needs, computerization has developed to the point where there are now a number of clinical laboratory systems which support total laboratory automation. Capabilities include information processing, order and result entry, immediate variable-format laboratory reports, inquiry networks, and communication systems (227). The physician is provided with a sing[illegible] cumulative, computer-generated laboratory report for an individual patient with information [illegible]om all laboratory sections. These new systems are active and interactive in the

communication process. Thus, not only can computerized instruments carry out many of the technical functions of the testing process (including the normally labor-intensive process of specimen preparation for analysis (176)), they can also assist in interpretive analysis of results (165), warn of possible drug interference with test results (78), and monitor infection and antibiotic control (146).

Pharmacy. Automated pharmacy systems, like laboratory systems, have been developed to meet both internal operational needs (order entry, label production, inventory control) and interactive informational problems (medication profiles, duplicate medication screening, detection of potential adverse drug reactions). A number of tools and techniques have been developed to aid the pharmacist, among them (a) patient profiles, (b) automated counters and pourers, (c) drug interaction detection aids, (d) drug use review, (e) patient education, (f) continuing education for the pharmacist, (g) time and motion analysis, and (h) poly-drug prescriptions (36). Pharmacy computer systems have been shown to provide more comprehensive service than do manual operations while at the same time reducing errors, costs, and time needed to perform functions. In a paper regarding pharmacy information systems in multi-hospital health care systems, Trusty (194) observed that:

> In approximately the same time that a pharmacist now spends typing one label, the computer processes the prescription, prints the label, reviews the patient medication file, screens for allergies, updates management information, and performs inventory control functions. In addition, the computer provides a drug information capability that pharmacists cannot duplicate in the traditional practice setting (p. 868).

In 1977, the Naval Regional Medical Center, Charleston, South Carolina, installed a pharmacy information system to test the feasibility of a total pharmacy computer effort (132). Despite a considerable climb in prescription volume, the computer's speed and accuracy, coupled with automated dispensing services, significantly reduced both patient waiting time and total pharmacy expenditures. In addition, the pharmacy has bee. able to intervene on a number of occasions to alert physicians to drug-allergy or drug-drug interaction conditions that could have been harmful to the patient had they gone undetected and uncorrected. The primary advantage of the Charleston system is that it enables the pharmacist to do more with less, for less, while maintaining and even upgrading quality of care.

Radiology. Radiology is one of the most costly health services. It includes the use of X-ray and isotopes, both in diagnosis and treatment, as well as the newer use of medical ultrasound. All of these areas are strongly affected by the growing use of computers (49). Computer-assisted treatment planning and dosage calculation are used routinely in radiation therapy throughout the world (50), and the computerized 3-D modeling of anatomical structures (Computed Axial Tomography) is developing rapidly.

One of the more prominent problems to which computer solutions are being applied concerns the reporting and recording of the radiologist's X-ray interpretations. Experience in various hospitals indicates that it takes from one to five days to produce this report and get the information to the referring physician (199). Recent computer developments, however, enable radiologists to construct their interpretation reports on-line.

A fully automated and comprehensive radiology department system was implemented at the Universty of California, San Francisco, in 1980 (152). It is composed of modules which include

patient registration, patient flow control, film trading, reporting, pathology coding, management statistics, and billing. In addition, this system interfaces with key systems outside the radiology department, and thus functions as one mode in the larger, integrated, distributed hospital information system. The Navy Medical Department, in conjunction with the Army and Air Force, is also in the process of developing a fully automated, modularized, radiology management information system (155). System procurement has been scheduled or completed for Navy facilities in San Diego, Oakland, Long Beach, Bethesda, Portsmouth, Jacksonville, Pensacola, Bremerton, Charleston, Camp Pendleton, and Camp Lejeune.

Electrophysiology. Computer-assisted analysis of electrophysiological signals (EEG, EMG, evoked potentials for auditory and visual nervous system activity) is being used intensively in the field of neurophysiology (27, 108, 109). In addition, the high workloads, staffing shortages, tracing storage and retrieval problems, and scarce cardiological resources associated with managing the ECG are being successfully met by the Computer Assisted Practice of Cardiology (CAPOC) Project now functioning at 21 Navy and Air Force medical treatment facilities throughout Southern California (16). The CAPOC Project's first priority is given to input, interpretation, and output of preliminary ECG reports, but its usefulness extends to many other functions as well. Among the benefits demonstrated at NRMC, San Diego, are a clear, concise, standard ECG report format, a quality control check of th ECG signal, the capability for remote consultation and record transfer, and greatly improved sto: ,e and retrieval capabilities. The system is undergoing continued refinement and improvement.

Nutrition. Computerized analysis of diet is only in its formative stages, but it is already being successfully employed in individual diet counseling and research (65, 189, 193). A recently implemented program for counseling children with cystic fibrosis is proving more successful than the direct advice from a caring dietitian--apparently because children seem to have a special affinity for computers. Children as young as 6 or 7 years old are learning to run the program themselves and are enjoying it as a game that happens to be educational (189). But the real value of the computer in nutrition counseling lies in its ability to handle two of the biggest problems encountered when working with nutrition information: the very large amount of data involved, and the lack of conclusive evidence for many nutrition-health interactions (127). The latter is a complicated research problem that cannot be resolved without detailed studies and powerful data management techniques, such as those provided by computers.

There are, however, some inherent limitations in computerized diet management. One limitation is that viable diet history depends on patient compliance and accuracy in recording foods eaten. Another is that food composition tables represent average nutrient values and cannot account for the effects of ripeness, storage, and cooking. Recommended daily allowances are also average values, based on average human bodies and average food nutrient values. Solutions to these and other issues must await advances in software development and a more precise understanding of the physiology of nutrition.

Major Evaluation Projects

Little Report. Since the 1960s, the federal government has funded a number of projects and reports that have collectively encouraged the development of hospital information systems (95). The

1971 Arthur D. Little report, "Systems Analysis for a 'New Generation' of Military Hospitals," is one of the better known efforts and is highly relevant to military medicine (112). This Department of Defense-sponsored project called for the evaluation of all new technologies, including hospital information systems, that could be utilized in the staffing, training, organization, design, and procedures for care in the generation of hospitals to be built or remodeled in the 1970s and after.

The nine-volume final report included an outline for the proposed features of a prototype hospital designed to test the new concepts and recommendations identified in the study. Of these concepts, the reorganization of ambulatory care to make more use of nonphysicians was considered to afford important savings and benefits. Modest savings and benefits were anticipated from the increased use of automated equipment (including computers) in the laboratory. Those concepts which, in 1971, had enough promise to warrant further research and development were (a) automated hospital information systems, (b) computer applications such as history-taking, report composition, and computer-aided diagnosis, and (c) remote consultation by television.

Henley Report. In fiscal year 1975, the National Center for Health Services Research contracted for a major study on the state of the art in automated ambulatory medical record systems. Ronald Henley, Gio Wiederhold, and a number of other researchers, under the auspices of the University of California, San Francisco Medical Center, surveyed the 175 known sites where an AAMRS of some kind was in operation. Following this comprehensive review, they undertook an extensive evaluation of the 17 most advanced and representative sites. The study generated a large amount of comparative data which included user objectives, designer objectives, computer language used, terminal type, means of data entry, development and operational costs, benefits obtained, and problems encountered with various systems at each of the 17 sites. Results have been published in a detailed, two-volume report (86).

Although the project was intended to be a survey of the state of the art of AAMRSs (circa 1974-1975) rather than a source of design recommendations for future systems, a number of guidelines are suggested in the general findings of the research team. No one system was found to be ideal in satisfying all the requirements that might be placed on an AAMRS, but some of the systems did succeed in providing all of the services that their designers had intended. Likewise, no single technical approach--e.g., local or remote, large or small computers--was found to be superior in all instances. Where lack of system reliability was found to be a problem, it was due primarily to communication problems among people, not to computer hardware. In fact, in those instances in which team care was provided, the AAMRS often served as a communication aid among members of the health care team.

The Henley report attempted to evaluate the general utility of data being collected at the various sites. Results suggested that the utility of an automated data base was more dependent upon a clear, concise format than upon the specific content of the data. A data abstract or patient profile was considered to be one of the most valuable outputs of an AAMRS, yet formatting of flow sheets was often so poor as to inhibit rather than facilitate scanning. Output was also too long--sometimes several pages in length--and redundant. A concise, well-formatted flow sheet with various parameters displayed over time was recommended for physicians; simple graphs of population-based statistics and group comparisons, on the other hand, were considered to be more useful for management.

Checklists or dictaphone entries were the predominant means of data collection at the sites visited. Having the physician type data directly into the computer was too slow and inconvenient. Consequently, the researchers suggested a brief (one-page) encounter form in problem-oriented format, with both precoded entries (such as a checklist) and free text provided for on the form. Automated surveillance of patient records, designed to remind the physician when checkups or certain procedures were due, was considered useful but costly. Such prevention-oriented applications of AAMRSs were therefore usually given low priority.

One of the most popular applications of the AAMRS was for appointment scheduling and patient registration. Automation in this area saved time, improved efficiency, and reduced no-shows. However, those advantages were seen mainly in large clinics, such as county or federal settings. Smaller offices, lacking the logistical problems of large operations, have less need for and would consequently derive less benefit from automated scheduling and registration. This highlights the fact that evaluation of the benefits and operational effectiveness of an automated record system depends in part on the size of the population being served. The researchers found that with a large patient population, even simple automated services, such as scheduling, could significantly improve access to and quality of medical care.

Providers, however, were generally not convinced of the value of automated records over paper records. The research team believed that this was because the providers' focus is narrower than that of AAMRS developers. That is, the potential of AAMRS for management, planning, evaluation, and research is either not seen or not valued by providers whose interest is in the immediate positive effects on patient care. At all sites surveyed, Henley et al. noted that the active participation of medical personnel in the development phase of an automated medical record system was essential in order for benefits to later accrue from system use.

Inadequate data were available to evaluate either the effects of medical record content on the quality of patient care, or the cost-benefit balance of gathering and automating patient data. However, the report did provide the following observation concerning funding, which is of special import to the Navy's automation program:

> In the funding arena, it was shown that the sites which have received significant amounts of Federal funding have not planned as well for financial viability as sites funded from other sources. Complaints were heard from the Federally-funded sites that the indications for the direction of the research and development to be emphasized change faster than the time interval required to bring the previous objective to maturity. The lead times for development of AAMRS's are unbearably long. (86, Vol. I, p. 12).

El Camino Hospital Report. Plagued with rising labor costs, underutilization of professional nursing skills, and a growing mountain of paperwork, the El Camino Hospital, a 464-bed facility in California, agreed to serve as the pilot hospital for demonstration and evaluation of a total hospital information system. Because of the developmental nature of the project, it was agreed that implementation costs of the Lockheed-designed system would be borne by the vendor. When findings from a four-year evaluation of the system were reported in 1977 (66), total investment in the development of the system was estimated to be $20 million dollars.

Early design concentrated on business needs, followed by the development and implementation of the clinical elements of the system. The completed system is capable of computerized handling of medical records and drug files. It also provides a means for ordering medications, nursing services, and all other patient services. A broad range of both medical and administrative data are processed by the computer.

The timeliness and accuracy of the information, the immediate availability of the data, and the assumption of clerical tasks formerly performed by hospital personnel have yielded the most direct benefit to patient care. Patients have also benefited indirectly from the physician support capabilities of the system, such as assistance in ordering diagnostic tests, interpreting clinical results, and prescribing therapy. A comparative laboratory report, designed to permit rapid comparison of test values over time and across categories, has proven to be one of the most valuable interpretative aids. Therapeutic aids include drug and allergy information and a communication link with the pharmacy.

It is to be expected that a system under development will be incomplete at first and suffer from operational difficulties such as "bugs," system failures, user delays, and promised capabilities which are not yet functional. Learning to work with a new system, especially one that is not yet highly refined, can be frustrating and alienating to users, and the physicians at El Camino Hospital were no exception. Unfortunately, their initial aversion to the system lingered despite system improvements, and physician acceptance and utilization remained a problem. Gall (66) points out that physicians new to the hospital since full implementation of the system have had no difficulty learning to use it, and they use it quite readily. He speculates that many of the original users are unaware of the number and extent of improvements made since their initial painful experience. Overall, however, the project has been considered a success. Reduced errors, improved timeliness, and enhanced availability of medical information, combined with the favorable economic impact--the system has proven to be cost-effective, with labor savings accounting for 95% of the total savings derived--have made the El Camino Hospital project a vanguard of the total hospital information system concept.

TRIMIS. By far the largest and most ambitious effort to develop and assess automated data processing (ADP) techniques for health care delivery systems is the Tri-Service Medical Information System (TRIMIS) Program (18, 193, 195). Although some of the recommendations from the New Generation of Military Hospitals Project were introduced into certain facilities, the prototype hospital was never built, and in fact no overall plan for ADP implementation existed. To meet this need and to avoid duplicative development and acquisition efforts by the three military services, the Deputy Secretary of Defense established TRIMIS in 1974. The primary mission of the program is to improve the effectiveness and economy of military health care service through the application of standardized ADP techniques. A secondary objective is the centralization and coordination of efforts toward this end. The strategy has been to acquire, develop, and test several pilot systems with various capabilities in selected hospitals, including the following Navy facilities: NNMC Bethesda, NRMC San Diego, NRMC Oakland, NRMC Charleston, and NRMC Portsmouth. Utilization of existing technology has been emphasized.

The TRIMIS Program Office has delineated three distinct procurement steps for fulfilling its mission (195). The first stage entails acquiring a limited number of systems to satisfy the immediate needs, identified by the Surgeons General, for ADP support in radiology, pharmacy, clinical laboratory, and patient appointment scheduling. Stage two will involve the interface of these four functional systems, along with expansion of functional support to include additional work centers. The final stage will involve the procurement of a sufficient number of integrated

systems to support all military treatment facilities justified by the three Services. This effort should culminate in a consolidated, fully standardized network of integrated ADP systems interlinking all military hospitals. For now, however, the project group is proceeding cautiously; most of the current programs apply to only one Service in any given region. To date, TRIMIS has installed several operational support systems. Within the Navy these include pharmacy, clinical laboratory, ECG analysis, radiology, pulmonary, health care, testing, diabetes management, and patient registration services.

Several new developments were discussed at the First Annual TRIMIS Program Conference at Bethesda in June 1982. For example, pilot projects to implement automated outpatient medical record systems are currently underway at the Fort Ord Family Practice Clinic (135) and the Pease AFB Family Practice and Primary Care Clinics (56). Both installations are using COSTAR (Computer Stored Ambulatory Record), a commercially available system selected for its proven capabilities. COSTAR is discussed in more detail in the systems design section of this paper.

A second new development concerns the procurement and installation of commercial hospital information systems in three facilities, one nominated by each of the Armed Services (34). This program is in response to a joint House and Senate Appropriations Committee directive, which reflects the computer industry's contention that integrated medical information systems may provide more capability than the piecemeal installation of individual functional systems that TRIMIS is undertaking. TRIMIS currently plans to evaluate the cost-benefit impact of the three systems.

Interfacing the major automated information programs in the Armed Forces represents yet another complex issue now under consideration. TRIMIS, UCA (Uniform Chart of Accounts), and DEERS (Defense Enrollment Eligibility Reporting System) are all major DoD-directed programs, and all three have now reached a point of operational capability where the information necessary to undertake interfaces has become available (126). But the technological problems, and more importantly, the impact that such a combination of systems would have on the field of health care delivery, have become a serious concern. Unnecessary duplication among these three projects, for example, would mean a substantial waste of time, space, and money. Similarly, the potential benefits and problems of such a herculean undertaking (DEERS alone has a data base of over 1.5 billion characters) requires close examination. Although interfacing has already begun (e.g., the pilot DEERS/TRIMIS interface implemented with the Tri-Service Patient Administration System at Keesler AFB), careful consideration of alternative strategies is important in order to establish directions and document requirements for further development.

INFORMATION NEEDS AND RESEARCH ISSUES

When computers first entered the medical field in the early 1960s, few practitioners could have imagined the extent and sophistication of the capabilities that would be developed for hospital information systems by the 1980s. Yet the successful development of information systems still requires careful forethought in terms of what data to collect, how to organize and store the data, and how to retrieve, analyze, and apply it. Without sufficient forethought, the computer will become the 'black box' of yesteryear, filled with information that no one can access and use (145). Without some assurance of fruitful utilization of information (assuming sufficient consideration has

first been given to the requisite transformation of raw data into potentially useful information), it is difficult to justify the systematic collection of large amounts of data (219).

It stands to reason that the data that will be most useful, hence the data that should be collected, are the data that providers and managers need to carry out their duties. Unfortunately, most users fail to realize what Kerr White (215) droily refers to as "Finagle's Laws of Information," which are:

> The information you have is not the information you want!
> The information you want is not the information you need!
> The information you need is not going to be available until the health administrator and statistician start collaborating closely! (p. 310)

Collaboration should be guided by a mutual understanding of the purposes for which the system is being created. Although these purposes will be tailored to the aims and particular needs of the individual facility (220), the consultants on Ambulatory Medical Care Records of the U.S. National Committee on Vital and Health Statistics suggest the following objectives to meet the needs of care givers, business managers, and researchers (144, p. 229):

1. Patient management. To assist the physician in caring for his patients and managing his practice.

2. Physician evaluation. To facilitate self-evaluation by the physician and professional review.

3. Epidemiology research. To provide the medical profession epidemiology with a better understanding of the natural history of health problems, complaints and diseases.

4. Administrative management. To assist those responsible for the management of office practices, clinics, group practices, hospital based ambulatory services, and other settings where ambulatory medical care is provided, in planning services, in allocating personnel and other resources, and in monitoring costs.

5. Medical education. To assist medical educators in clarifying the objectives of their curricula for medical personnel and health services administrators.

6. Regional planning. To support the efforts of local, state, and national agencies, health departments, medical foundations, and regional medical programs in formulating objectives, plans, and policies for improving health care services.

7. Insurance billing. To serve the needs of private insurance carriers, Blue Cross and Blue Shield, the Social Security Administration and related federal payment programs, and to permit the development of uniform insurance claims forms and patient billing forms.

8. Health services research. To provide epidemiologists and other health service investigators with sampling frames for research designed to improve the impact of health services.

Once the general purposes of the system have been outlined, the facility's specific informational and technological needs are determined by the lengthy and iterative process of systems/needs analysis. The following section will describe some of the general information requirements of an automated record system and address the particular data needs of outpatient medical records. Next, a review of numerous shortcomings of present data collection efforts will highlight the kinds of problems that an automated system should solve. Finally, because many of these shortcomings are felt most acutely by researchers and program evaluators, the special problems and information needs of clinical researchers will be explored. This section concludes with a discussion of the role of automated information systems in quality assurance.

Needs Analysis

Systems analysis is the vital first step in the actual design and implementation of a hospital information system (5, 10). It should be undertaken by a carefully selected team of people, some of whom know the hospital well, others who have technical knowledge of systems analysis and design

techniques. All levels of hospital personnel--physicians, administrators, paramedical and support services--should be represented on this committee in order to insure staff participation and cooperation in the total automation effort. The object of the analysis is to document the flow of information throughout the hospital. Subsequent study of this documentation can then be used to specify functional requirements, clarify existing problems, and determine how the present process must be modified to facilitate implementation of a computerized system.

Austin (5) suggests that the committee address questions such as: What are the weaknesses of the present system? What are its strengths? Why is a new system needed? What specific kinds of information need to be available? Who will use it? In what ways will it be used? Where does the needed data originate? Other questions will arise with respect to the choices of what to automate and how. For instance, which part of the medical record should be automated--all of it? Part? Which part? How do you decide? (56). Which data items should be routinely collected on a 100% basis? Which on a sampling basis (e.g., 10%) or variable collection (e.g., 100% of one item one year, 100% of another the next year, etc.)? (4).

As research literature consistently points out, these questions can really only be answered for (and by) facilities on an individual basis (84, 129, 158, 173). The defined data base which emerges from a careful systems/needs analysis will be different for different doctors, practices, specialties, and groups, and for different patients of different ages. There are, nevertheless, certain considerations that are common to virtually all medical centers, and certain recommendations that have general applicability. A well-conceived medical database should primarily serve clinical practice (145), though a simple system founded on clinical information can probably do double duty, perhaps with some minor modifications, and serve researchers and even certain administrators as well. Core information items should be selected according to their utility, feasibility, uniqueness, and scope. Items should be (a) useful to the majority of potential users on a routine basis, (b) readily collectable with reasonable accuracy, (c) uniformly defined to facilitate common understanding and use, and (d) applicable to more than one data system or organization (131).

The fourth requirement--that data have broad applicability--reflects the fact that discrete hospital functions frequently make use of the same data elements. A single large data base can contain many types of records and serve a variety of users (218). However, because the aims and actual utilization of data may differ radically among different kinds of decision-makers, Ueno, Saito, and Kaihara (196) recommend designing and maintaining separate, interfacing data bases to serve administrative, clinical, information service (e.g., blood bank), and research needs (195). Reps (156), on the other hand, suggests that the information system should be conceptually divided into hospital <u>functions</u> and data <u>files</u> (e.g., patients, physicians, accounts), with the latter designed to support the myriad activities of the former. This solution manages to introduce clarity without making the database an end in itself. The essential point in either design is to avoid repeated collection of identical items for different purposes, and to view the total health information system as an interlocking set of subsidiary systems (4).

Information needs are determined by both internal and external requirements. Internal needs reflect the organization's objectives and structure; external requirements arise in conjunction with an organization's functional relationships with other agencies (51). Internal information needs are

of primary concern for the day-to-day operations of the agency; in most cases, information used within the organization is simply excerpted and/or summarized to satisfy external requirements. A hospital information system is usually set up to be patient-based and hence geared toward meeting internal needs. Such systems customarily establish one or more files (medical records) for each patient. These files encompass data related to intake/history, observation, diagnosis, and treatment (107). Information gathered might include demographic and identifying data (age, sex, occupation, etc.), family history, presenting problems, medications currently being taken, allergies and sensitivities, physical findings, laboratory data, diagnoses, physician's orders, treatment, therapy given, progress notes, provider's name, date and place of contact, referral sources, and financial status (107, 129, 157, 158, 226).

The amount of data gathered varies considerably from one facility to another, and the question of what is the ideal or appropriate database naturally depends on the type of practice and the patients and problems encountered. It would be useful for planners to look at what others have done in their needs analyses, except that very little has been done. D'huyvetter's (51) comprehensive report for the National Institute of Mental Health, however, represents a notable exception. Although this study focused on information needs in a community mental health center, the detailed analysis of data elements and information necessary to satisfy program management and accountability requirements could serve as a guideline for other large health care centers. D'huyvetter summarized her data elements in general tables that describe Who Delivered, How Much, of What Service, To Whom, When, in Which Program, at What Location, with What Results, at What Cost, reimbursed at What Fee, using What Source of Funds. Those tables were supplemented with summary lists of other types of information required for agency management, administration, reporting, and accountability.

The structure of D'huyvetter's analysis is very similar to that proposed by Hoeffler (92) in an internal Navy memorandum. In this memorandum, Hoeffler outlined the major information requirements for a Navy management information and decision support system for health care programs. Such a system should describe Who is sick, for What Reason, with What Frequency, for How Long, in What Locations, at What Cost, and with What Variations. In addition, the system should (a) initially utilize currently available data services, (b) provide a logical basis for the allocation of resources and establishment of program priorities, (c) provide a basis for the development of needs indicators for clinical and non-clinical resources, (d) utilize the diverse talents of health researchers, computer technologists, administrators, systems analysts, and others within the various Navy Medical Command agencies, (e) highlight periodic and cyclic changes and trends among elements of the health care system, and (f) be subjected to periodic evaluation and adjustment. Lastly, the system should minimally contain data concerning the populations served (by age, sex, race, entitlement status, IUC/RUC), morbidity/mortality information (by age, sex, race, entitlement status, case mix, severity, etc.), medical department resources used, community resources used, sources of medical care (by diagnosis and case mix), and noneffectiveness days.

Outpatient Medical Records

Hospitalized patients represent less than 5% of the total of annual medical contacts in the United States and Canada; the vast majority of health care is delivered on an outpatient basis (137). Navy Regional Medical Centers, like other large, multi-hospital health care systems, place

special emphasis on ambulatory care in an effort to minimize costs (17). In fiscal year 1980, outpatient visits in naval medical facilities totaled nearly 14 million (or nearly 38,000 per day), while the daily average inpatient load was less than 3,300 at these same facilities (31).

Yet despite the heavy utilization of outpatient services, the availability and accuracy of outpatient medical records are less than optimal. Unlike inpatient care, where events are concentrated, the information markers in ambulatory care are spread over relatively long periods of time (180). Moreover, the hospitalized patient is assigned a bed where he remains for the duration of treatment. The ambulatory patient, on the other hand, can disappear before treatment or follow-up is complete, and perhaps reappear later with no record of any intervening medical conditions or services that might have occurred. The typical lack of continuity in primary care, the time intervals between visits, the brevity of contact with any single provider, and the number of contact points to which the record must travel during any one visit all contribute to the poor quality of surviving ambulatory records (many are lost).

The automated ambulatory medical record system represents a potential solution to many of these problems. The Uniform Minimum Basic Data Set for Ambulatory Records provides a logical starting point for describing information to be collected in these automated records (197):

<u>Basic Data Set for Ambulatory Medical Care</u>

A. Items that characterize the patient

   1. Patient identification

      a. Name: Surname, first name, middle initial

      b. Identification number: A unique number that distinguishes the patient and his ambulatory medical care record from all others

   2. Residence: Patient's usual residence, to consist of street name and number, apartment number (if any), city, state, zip code

   3. Date of birth: Month, day, year

   4. Sex: Male, female

   5. Expected source of payment

      a. Government program

         1. Workmen's compensation
         2. Medicare
         3. Medicaid
         4. Civilian Health and Medical Program of the Uniformed Services
         5. Other (specify)

      b. Insurance mechanism

         1. Blue Cross
         2. Blue Shield
         3. Insurance company
         4. Prepaid group practice or health plan
         5. Medical foundation

      c. Self-pay

      d. No charge (free, charity, special research, teaching)

      e. Other (specify)

B. Items that characterize the provider

   1. Provider identification

      a. Name: Surname, first name, middle initial

      b. Identification number: A unique number that distinguishes the provider from all other providers

2. Professional address: Street address, office number (if any), city, state, zip code

3. Profession

   a. Physician (include specialty, if any, as determined by membership in, or eligibility for, specialty board)

   b. Dentist (include specialty)

   c. Nurse

   d. Other

C. Items that characterize the patient-provider encounter

   1. Date of encounter: Month, day, year

   2. Place of encounter

      a. Private office

      b. Clinic or health center (any except hospital outpatient department)

      c. Hospital outpatient department

      d. Hospital emergency room

      e. Home

      f. Other (specify)

   3. Reason for encounter: The patient's problems, complaints, or symptoms on this encounter, in the patient's own words

   4. Findings: All history, physical examination, laboratory, and other findings pertinent to the patient's reasons for visit or diagnoses, or both, and any other findings the provider deems important

   5. Diagnosis and/or problem: The provider's current assessment of the patient's reasons for the encounter and all conditions requiring treatment, with the principal diagnosis and/or problem listed first. Principal diagnosis and/or problem is defined as the health problem that is most significant in terms of the procedures carried out and the care provided at this encounter.

   6. Services and procedures: All diagnostic, therapeutic, and preventive services and procedures (including history taking) performed during the encounter and those scheduled to be performed before the next encounter.

   7. Itemized charges: All charges to be made by the provider for services and procedures performed during the encounter or to be performed by him or his associates before the next encounter.

   8. Disposition (one or more)

      a. No follow-up planned
      b. Return, time specified
      c. Return, P.R.N.
      d. Telephone follow-up
      e. Referred to other provider
      f. Returned to referring provider
      g. Admit to hospital
      h. Other

Schleich and Hurst (169) suggest using this list as a core, then expanding it by listing the information asked for on all forms used in the practice. Such a process would reveal collection of duplicate data and enable the design team to develop more streamlined forms and data collection procedures. But before doing that, each data element should be carefully examined for its usefulness: What good does it do, how is it used, what would be the consequence if it were no longer collected? Routine data is necessary only if it is used often enough to justify the cost of collection and processing. The resultant pared-down master list of data elements could then be grouped in various ways--by department or by management use, for example. Key personnel in the hospital departments involved in the information system should be interviewed to document present

procedures, provide input regarding information needs, and review the proposed list of data elements (5). Any information identified as useful but not currently being collected should be noted on a separate list and incorporated into the new master list. Forms redesigned accordingly should be tested for efficiency and utilization. Revised procedures for data collection should be tested in the same way. The procedure described above is used to identify internal data requirements; external requirements are generally straightforward and already formally defined by the requesting agency.

The traditional medical record has been acknowledged to be cumbersome, disorganized, and redundant; information is difficult to find and nearly impossible to follow serially (64). Complex temporal relationships between clinical, laboratory, and therapeutic events are not indicated, nor can they be with the standard record format. Clinical rationale is not included with diagnostic and therapeutic decisions, which hinders evaluation as well as the formulation of alternative hypotheses by other observers. Many important details are omitted, rendering the information that is recorded too imprecise or incomplete to be useful.

Several critics, in pointing out the informational weaknesses of the traditional medical record, have indicated some of the conceptual shortcomings and linkage problems that must be solved before content can be utilized in a meaningful way (57, 64, 94, 101, 219, 226). A number of suggestions have been offered for improving the medical record:

1. The medical record should (a) encourage the monitoring and analysis of outcome parameters, and (b) facilitate corrective actions (226).

2. Medical data forms should be flexible enough to accommodate the wide variety of patients and the impact of time variables (94).

3. Medical data forms should be standardized (94).

4. Relationships among all items in a medical record should be analyzable (94).

5. Subjective data are medically important and should be included in a usable way (94).

6. Large portions of the medical record are seldom utilized and need to be handled in more expeditious manner (94).

7. The medical record should include the physician's reasoning along with data supporting medical decisions (57, 64).

8. Representations of time relationships (graphs, dosage schedules, etc.) should be unified and displayed in a single format (64).

9. The conventional, chronological, source-oriented document should be replaced with a problem-oriented medical record (57).

10. Clinical information (such as "severity of pain") needs to be elaborated (e.g., does the pain impair sleeping, eating, working?). Progress notes and outpatient notes also need to be more extensive in order to assess the impact of treatment (57).

11. Follow-up data should be included in the record (57).

12. Most medical practices need a more elaborate information retrieval system than the usual one of patient name and/or chart number (69).

Finally, lest anyone continue under the delusion that technology alone will produce quality data, or that technologic hardware can stand in for careful clinical thought, Feinstein (57) concludes his critique with the following uncompromising remarks:

> We cannot escape the need for using our human talents in this work, but we can make the resultant data much more reliable if doctors will pay primary scientific attention to our own methods of examination, rather than to laboratory techniques and extrinsically automated procedures that get precise, quantifiable, reproducible answers to the wrong questions. The greatest need of clinicians today is not for more technologic innovation, but for an intellectual reorientation that will lead us to develop greater objectivity, precision, and specification in our examining procedures, and that will be accompanied by the establishment of rigorous criteria for each of the intellectual maneuvers used in transforming the observed evidence into the interpreted conclusions. Without these improvements in the methods of acquiring data, in the choice of data to be acquired, and in the intellectual algorithms used to interpret the data--the results will remain scientifically inadequate for the needs of medical practice (p. 434).

Clinical Research

Although the most immediate and obvious purpose of medical data is the clinical management of the patient, the analytic scientific investigation of clinical events serves to document successful diagnoses and therapies and to develop better methods of care. Retrospective studies involving paper records, however, require an immense amount of time and effort to sift through individual records and tease out the information desired. Prospective studies are even more problematic. These studies are expensive and complicated to administer, usually require that large groups of subjects be followed for long periods of time, and frequently become biased by sample decay, as patients move out of the area and can no longer be tracked (105).

As information systems are developed for outpatient use, there are a number of general research data requirements that should be satisfied with routinely collected data. White (215) proposes the following eight guidelines:

1. The data should be person-specific. The information system should have the capacity to describe health problems, attributes, events, activities, services, and outcomes, for example, in terms of the numbers of individuals possessing them.

2. The data should be population-based. The system should be able to make comparisons within and across jurisdictions and over time.

3. The data should be problem-oriented. Identification, labeling, classification, and counting of people's perceived health problems should be accomplished.

4. The data should be provider-specific. Provider and location of service provided should be identified.

5. The data should be procedure- or process-specific. The system should have the capacity to identify the forms of therapeutic intervention used.

6. The data should be period-specific. The system should be able to relate persons and places over periods of time. (The type of time interval used, e.g., time of day vs. day or week, will depend on what is being monitored).

7. The data should be practical. That is, the collection process should be made as efficient as possible to minimize respondent burden, and the data collected should serve multiple purposes.

8. The data should be parsimoniously selected. Only those data having a high probability of meeting a predetermined need should be collected. When in doubt, leave it out.

Sibley, Hopwood, Grover, Josephs, and Palley (178) designed a prototype data management analysis system intended for the personal use of physicians engaged in clinical research. The system was predicated upon three observations regarding research data: (a) The fundamental unit of analysis is usually the patient, (b) data about the patient are collected over time, and (c) the data have a natural grouping in time (for example, vital signs are sampled at essentially the same time). Because changes in clerical variables over time are critically important for the evaluation of patient course, prognosis, and response to therapy (64, 113, 151, 157), the system developed by Sibley et al. highlights the individual patient and the time-oriented nature of clinical research data.

The following examples of typical clinical studies illustrate both the kinds of information needed for clinical research and the utility of automated data processing in meeting those needs. A clinical trial is a controlled experiment designed to test the effects of a medical treatment on human subjects. It requires detailed analyses of the medical status of large groups of patients followed over long time spans. Long and Brashear (113) describe the logistics of a national multi-clinic clinical trial as follows:

> The hyperlipidemia clinical trial is a definitive test of the lipid hypothesis. It is designed to seek an answer to the question of the effect of maximal cholesterol reduction on patients with known atherosclerotic heart disease. One thousand patients are being randomly assigned to either a treatment or a control group. The patients will be followed for five years after randomization. Periodic clinic visits are scheduled to ascertain the extent of atherosclerosis and to detect the occurrence of any other medical problems. Trial protocol requires a highly restrictive recruiting and screening process to obtain 1,000 patients for randomization. It is anticipated that clinical data will be collected from at least 10,000 patients during the screening phase of the trial. Twenty-two different forms are used for data collection. They range in size from a single log-in report to a 31-page medical history and physical form. Obviously both patient management and data management are primary concerns of the trial (p. 59).

At Stanford, computer analyses were used to predict the likelihood of a given patient developing specific complications of rheumatic diseases (157). Predictions were based on data collected from similar patients. Also at Stanford, a computerized database search will quickly generate a scattergraph of any two selected medical variables for all patients with a given diagnosis. At the Medical University of South Carolina, residents can undertake database searches for specified interactive variables (157). These searches can be used to identify special risk groups or populations of interest, e.g., all those patients under age 45 with a blood pressure greater than 150/100, on thiazide medication, and with a potassium level of less than 3.5. Westlin, Cuddihy, Bursik, Seifert, and Koelle (213) reported using an automated information system to carry out a systematic evaluation of adverse drug experience data within a pharmaceutical firm. In this type of evaluation, data gathered during careful post-marketing surveillance of adverse drug incidents are trend-analyzed, then reported to the U.S. Food and Drug Administration. These studies represent a few of the many applications of automated databases in clinical research.

Epidemiological Research

Epidemiology is the study of the distribution and dynamics of disease in human populations. Its purpose is to identify specific agents or factors which may cause a disease or which may identify people who are at high risk for developing a disease. In addition, epidemiologic methods are essential for evaluating the efficacy, or possible harmful side effects, of new preventive and/or therapeutic measures, for determining the effectiveness of new patterns of health care delivery, and for examining the cost-benefits of health care (73).

The case-control study is the method most commonly used to determine what factors increase the risk of contracting a disease (105). In such a study, a group of people who have the disease are matched on a number of sociodemographic variables with a group of control subjects who do not. If a certain kind of exposure appears more often in the medical histories of the experimental group than among the controls, the exposure is presumed to enhance risk of contracting the disease. A sound diagnostic archive can greatly facilitate such research.

Modern epidemiologists are moving away from an exclusive concentration on etiological factors and adopting instead a broader ecological or psychobiological orientation (214). This new approach takes into account the human host as a psychobiological respondent to noxious stimuli as well as the

physical and social characteristics of the environment in which the agent-host interactions occur. It follows that a systems approach and a cybernetic model may be more useful for this new kind of epidemiological research than the traditional vital statistics coupled with morbidity mortality data.

If epidemiology is to achieve its full potential, more attention and research must be given to the presenting problems that occur in the early stages of ill health, before any classifiable disease is evident. Surveys should be undertaken at the community level on the prevalence of chest pain, headache, diarrhea, and shortness of breath, for example, as these can be more informative of health needs than can mortality statistics. Traditional outcome measures of mortality and changing incidence or prevalence rates of disease need to be supplemented with measures that capture changes in functional status, such as disability and discomfort (37, 129). This would greatly improve the meaning and interpretability of treatment outcomes, since the mobility of the population, the multiplicity of factors influencing disease onset and death, and the length of time required before any large change is evident all combine to make it virtually impossible to relate variations in styles of medical care to such outcomes as mortality or incidence/prevalence change (37). There is, therefore, a need in epidemiological studies to develop measures of disability, distress, discomfort, dependency, severity, intensity, direction, and limitation of functional capacity, in addition to basic demographic and clinical data (214).

At the 1973 Conference on Ambulatory Medical Care Records, the group studying research information needs proposed that diagnostic labels be standardized and that the physician's bases for establishing diagnoses be made explicit (129). It was felt that only then could diagnoses be assessed in terms of their validity and comparability when studying the nature and cause of disease. Thus, in addition to developing new process and outcome measures, researchers need to standardize--at national and even international levels--the terms, definitions, and classifications that they use.

Research Management

Clinical researchers face a complicated management problem involving the concurrent handling of subjects, study protocol, and data while simultaneously providing clinical care and maintaining quality control over all aspects of the study. Both the quality and the cost of a clinical study are affected by data management mechanisms; therefore, clinical researchers need powerful, reliable management tools and data processing capabilities to carry out their programs. Computerized data systems can be a most effective aid if the system considers all facets of the clinical research task.

The development of an effective database represents a primary concern in clinical research (218). Data to be encoded often include diagnoses, subjective findings, stages of disease, and patient demographic characteristics. Since exploration of a cause-effect relationship is the usual aim of research, data must, at a minimum, represent both events. Causal relationships, however, are rarely captured with a single snapshot. Because the outcome is usually delayed and unpredictable, a longitudinal database comprised of observations from a series of patient visits is required. With automation, the clinical researcher can readily handle the multiple, event-linked entries which constitute a longitudinal medical database. Without automation, the task is difficult or impossible, depending upon the scope and complexity of the study.

Palley and Groner (142) conducted interviews with clinical investigators at several different research sites in order to ascertain their information processing needs and practices. Respondents reported that the greatest impediment to their research lay in data analysis, probably because the majority of physicians interviewed relied on hand calculators and manual methods for their data processing. Their reasons for doing so varied, ranging from lack of understanding and/or difficulty with the process of getting data into the computer, to inconvenience and cost of using a computer. However, of those investigators who did use computers to perform complex analyses and modeling or simulation functions, most said that their research would not be possible without computer assistance.

The primary aim of Palley and Groner's survey was to develop a detailed understanding of the information processing needs of clinical investigators. When asked what procedures they used most often when analyzing their research data, the clinical investigators were almost unanimous in naming graphing and plotting, manual transcription, and descriptive statistics. Other frequently mentioned procedures included subsetting (i.e., selecting research subjects with common characteristics), complex statistics (e.g., regression analysis), and arithmetic preprocessing of data. A few respondents named modeling and simulation as well. Another series of questions asked which data manipulation tasks currently posed a "great" or "very great" problem for the investigators. Nearly one-half of the physicians mentioned developing computer programs, and one-third cited finding all patients with particular characteristics, complex statistical analyses, finding all values of a single variable, and adding new measures to all research records. All of these tasks are very amenable to computerization and suggest that automation could considerably enhance the clinician's ability to carry out research.

Unlike much research, most of the activities in a clinical study use as well as produce data as part of their normal processes. The data problem is further complicated by such factors as data volume, collaboration requirements, use of human subjects, and the changing nature of clinical research. Willard, Gatewood, and Ellis (221), therefore, have proposed a generalized model for a computerized data system to assist in the procedural, mechanical, and communications aspects of clinical research. Their model extends well beyond the traditional computer applications of data storage and retrieval. It deals with data control, study monitoring, user interfaces, report and analysis libraries, and study participant and support databases. The model also indicates that the role of computerized systems in clinical research could be expanded into such areas as automatic report generation and control, process control aids, quality assurance monitoring, and study documentation.

Research Problems

Research activities can be conducted by personnel within health care institutions or by outside researchers. Most commonly, health services research has been designed and managed by individuals or organizations that are not directly related to the health care practitioner or provider organization (187). The advantage of this approach is the availability of considerable resources (including time) and talents for the research task; the disadvantage is that it removes the researcher from the daily realities of the research setting. It is hoped that the emerging multi-institutional arrangements will facilitate more and better provider-sponsored research.

Other problems associated with health services research are due to the nature of the research database. Studies of the error structure in American federal statistics have led to suggestions for more attention to data quality (103), especially where large amounts of substantive data are concerned. Roos, Nicol, Johnson, and Roos (160) have described their experience with the comprehensive Manitoba Health Services Commission databank. Some of the specific problems for which they have developed quality checks include: coding errors, misidentification of individuals, individuals not covered for the entire relevant period, several registration numbers for the same individual during the relevant period, and possible unreliability of physician diagnosis. The specific issue of data integrity will be addressed in a separate section of this paper.

A problem characteristic of certain areas of medical research is the relatively small number of patients with comparable features. Before meaningful judgments can be made, either the sample size must be increased by including subjects from other hospitals, or the small sample size must be compensated by collecting data over a longer period of time (133). The first method is in many ways preferable to the second, but it gives rise to the problems of record linkage. Although the ultimate solution would be a national medical information register, this remains a controversial concept.

Sampling methodology represents a traditional research issue which must be given careful consideration when using clinical databases in which the data elements are fixed and subset identification may depend upon complex clinical decisions. Blum and Wiederhold (21) provide the following example of a simple trial to illustrate a number of the programming and database issues involved in the use of automated files.

Suppose that an investigator wishes to learn how the outcomes of patients with gouty arthritis who were treated with colchicine compared to a group treated with probenecid. Subjects would first be selected for gout, then further stratified by treatment. But this apparently simple problem is more complicated than it appears. Computer-based clinical trials are usually nonrandomized, which introduces bias into the subsets and necessitates a comparison of appropriate patient baseline characteristics in order to adjust for subset differences. Missing data and outliers may skew the results or, if they are omitted, severely diminish the resulting cell size. While an experienced clinician could probably determine the missing values on the basis of the clinical context of each record, a computer may require complex and elaborate software to emulate such clinical judgment.

Another problem is that of specifying the subsets to be used in the clinical trial. This specification may require the availability of data independent of the proposed investigation. For example, patients may have other diagnoses in addition to gout, or may be receiving other drugs in addition to colchicine or probenecid. The most conservative approach, that of including only those patients with no other diagnosis and no other therapy, is usually defeated by the limitations of cell size. Again, a clinician could review each record individually, selecting those cases in which another diagnosis was not concurrent with gout, or instances in which its concurrence was irrelevant, and do the same for confounding drug variables. But until such information is incorporated into the computer system, automated databanks will have these limitations in their research applications.

The problem of professional ethics represents yet another concern which is particularly acute in the use of automated databanks in epidemiologic investigations. Researchers are tasked with the protection of human subjects, including their privacy and the confidentiality of the data they provide. This protection is usually accomplished with the use of subject consent forms and the assurance of individual anonymity. In epidemiologic investigations, however, the information contained in medical archives and current medical records or databanks must often be available in an individually identifiable form during the time of the study (73, 129). To require that prior patient consent be given before access to medical records is permitted would make most studies impossible. Furthermore, redisclosures of information may also be important sometime after the study has terminated. Researchers must therefore devise strict but workable safeguards to insure confidentiality while permitting disclosure of needed information.

Quality Assurance

There are essentially three types of medical review which are performed by PSRO (Professional Standards Review Organization) committees. Medical care evaluation studies are retrospective analyses of a selected sample of patient records. These studies are conducted to document reasons for variations from criteria and to assure that deficiencies are corrected. Profile analyses are also retrospective and are conducted to determine and evaluate the patterns of care provided by a certain practitioner or hospital, or to determine the quality of care provided to a certain set of patients. Concurrent review, undertaken while the patient is still hospitalized, is performed to ascertain the medical necessity and appropriateness of admission and to assure that length of stay does not extend beyond that which is medically necessary (52, 118, 139, 140). The advantage of concurrent review, especially if its scope can be extended to the kinds of variables assessed in the retrospective analyses, is that it enables clinicians to monitor quality of care as it is being provided and to make any necessary corrections before the patient has been discharged.

Barnett, Winikoff, Dorsey, Morgan, and Lurie (15) draw a distinction between quality assessment (an attempt to measure the quality of care) and quality assurance, which is quality assessment combined with the systematic application of remedial measures to achieve improvement. The most desirable quality control program is thus the concurrent quality assurance review, for it implies a guarantee of standards of medical care to every patient, not just to those who are treated after a deviation has been detected in retrospective review.

A computer-based medical information system has been used to support a quality assurance review program at the Harvard Community Health Plan (15). Because data collection was an integral part of this facility's automated patient care recording activity, the program has been highly cost-effective. The largest expense incurred by medical quality evaluations is usually associated with the salaries of the physicians performing peer review; therefore, automation generally saves both time and money. It should be remembered, however, that physicians are required to develop the criteria used by a computer-aided system, and the development of criteria remains difficult and time-consuming (118). The Harvard Community Health Plan system utilizes concurrent audit to detect deficiencies in patient care, and automatic rapid feedback to the provider to permit timely correction of the problem. By effectively closing the loop between quality of care assessment data and their application to quality assurance actions, the automated program helps eliminate the unused

"orphan data" (134) that plague so many PSRO and medical audits. The system has been demonstrated to improve follow-up of throat cultures, and it is well accepted by the staff whose practice is being audited.

The information needed for quality assurance depends in part on the specific component of health care which is being evaluated--structure, process, or outcome (41, 48, 139). The structural approach focuses on the quality and quantity (or availability) of resources, including equipment, facilities, and personnel. Data include number, mix, organization, and qualifications of medical staff as well as space, equipment, and physical characteristics of the facility. Process measures assess the utilization of resources in the practice of medicine as evidenced in patient records or direct observation. Process studies are concerned with such questions as whether or not diagnosis and/or therapy have been appropriately conducted in terms of a set of criteria (e.g., medical standards or professional judgment). Outcome studies evaluate the end results of medical intervention. Usual outcome measures include mortality, disability, complications, and length of stay. Other outcome measures are being developed that include patient satisfaction, functional status, adjustment, and change in life expectancy.

The less than perfect relationship between process and outcome, however, has kindled a debate regarding which component is the better indicator of quality of care. Length of stay, an outcome measure, is one of the most commonly used (99). Fessel and Van Brunt (59) maintain that improvement in a patient's outcome is, or should be, the primary standard for measuring quality of care, and Feinstein (57) states that the way to evaluate treatment is to see what it accomplishes in patients (56). On the other hand, Lewis (110) failed to find significant associations between quality of processes and outcomes of care. In addition, Rasinski (153) points out that professionally sound care can nevertheless result in a negative outcome, while positive outcomes can occur in spite of incompetent care. In either case, the quality of care actually being provided is not adequately reflected in the outcome. Both sides agree on one thing: Neither process itself, nor the relationship between process and outcome, can be meaningfully evaluated until medical records, which are the primary source of information for quality assessment, are improved.

These deficiencies in medical records are particularly widespread in ambulatory health care. While quality evaluation has advanced considerably with respect to inpatient care, there has not been a comparable development of methods for outpatient review. Inadequate patient data, unreasonable evaluation criteria, and insensitive audit procedures hamper both ambulatory medical audits and inpatient audits (62). In addition, ambulatory care presents several unique problems (15, 41). Records are often handwritten and illegible. They are not uniform--the same data are not collected in each instance of a given problem--and they are seldom complete. There is no easily definable episode of illness in ambulatory care, and outcome is difficult to determine because many problems either are minor and self-limiting, or chronic and intermittent. Ambulatory problems do not correspond well to the discharge diagnosis labels that are typically used, hence clinic outpatients are less likely than hospitalized patients to receive a specific diagnosis. Because the physician has less control over an ambulatory patient's adherence to prescribed regimen than over inpatient compliance, the relationship between process and outcome is attenuated. Differences in the resources available among ambulatory care settings, and disagreements on basic strategies,

principles of care, and terminology, make it difficult or impossible to apply one evaluation method to all outpatient settings. Given these many problems, it will be necessary to devise new, outpatient-specific methods for measuring effectiveness. Patient records will be crucial to this measurement, since the alternatives--direct observation, patient interviews, and problem simulation--pose too many limitations for practical use (41).

Wirtschafter and Mesel (226) have proposed a four-step strategy for redesigning the medical record for quality assurance. The first entails selection of problem or disease entities which will reflect the facility's or clinic's purposes and goals. Step two is goal analysis, formulated in light of the scientific basis for diagnosing and treating the specific diseases outlined. Third, the indicators of goal achievement must be specified in terms of clinical values (such as blood pressure), appropriate conditions for measurement, and standards of the desired performance (e.g., not more than X value for Y amount of time). In the fourth step the detailed item lists generated in the first three steps are designated as a minimum care assurance data set and used to monitor patient outcome parameters.

Several recent studies have shown that providers can develop workable criteria, and that assessment of ambulatory care can be performed using these criteria (82, 144, 177). It is also encouraging to note that the number of clinics with active outpatient quality assurance programs is increasing (225). Although further research is needed to determine the overall impact of these programs, a number of very focused studies have shown improvements for specific criteria (28, 75, 122, 222). Other studies have documented the potential of computerized systems for aiding quality assurance programs either by facilitating the standards of care search (for example, providing a list of patients who meet the defined parameters of a given age group, sex, standard of care, and standard period of time between clinical tests (168)), or by improving the care actually provided (e.g., laboratory order completion, specimen collection, and results reporting systems (183)).

Occupational health monitoring systems are a special case of quality assurance in which computers combine clinical data with industrial hygiene information to help safeguard the health of the working community (150, 151, 163, 217). Relatively simple systems can produce measurable benefits. For example, a radiological protection service in Spain is using computerized file maintenance to improve the speed and quality of required reports and to exercise better control over permitted radiation doses (143). The system works by transmitting the evaluation of the radiation dosemeter directly into the database, where it is integrated with demographic data and data resulting from accidental overexposures or other emergencies.

A more comprehensive system has recently been developed at the Naval Health Research Center in San Diego, California (149, 151). This Navy Occupational Health Information Monitoring System (NOHIMS) integrates medical, environmental, and personnel data into a flexible health monitoring program suited to a variety of industrial and military settings. NOHIMS is capable of documenting environmental conditions in a full range of workplaces, identifying hazardous areas, documenting individual exposures to specified substances, providing a correlative list of recommended or required medical examinations/tests for exposed individuals, and providing data for epidemiological research.

DESIGN AND IMPLEMENTATION

The development and implementation of a hospital information system is a major undertaking. The desired system may be as simple as a single computer running in batch mode, or as complex as an on-line, real-time network of minicomputers. Regardless of the scope of the HIS, successful automation will require careful planning and decision-making. Not only must the most effective method for handling patient information be selected, but issues regarding (a) specification of system functions, (b) information networks, (c) database management, (d) database security, (e) hardware and software selection, (f) user acceptance, and (g) cost analysis must also be addressed (33, 83, 208). These and other issues germane to the design and implementation of an HIS will be discussed in the remainder of this section.

Specifications of System Functions

Many attempts have been made to depict hospital information systems as panaceas. Unfortunately, this trend has often over-accelerated the automation process, dictated the selection of application areas and methods, and reduced the likelihood that a hospital's particular problems would determine the specific application (188). To maximize the effectiveness of automation in a hospital setting, the system design process requires a source and application information study in which the following questions are answered about each piece of significant information to be automated (10, p.7):

1. Why is the information required and with what value and priority?
2. Who should initiate, process, receive, and utilize the information, and why?
3. What should be included, and why?
4. When should the information be gathered, processed, distributed, and utilized, and why?
5. Where should the above take place, and why?
6. How should the information be gathered, processed, distributed, and utilized, and why?

Answers to there questions will help define the traffic and use of all data. Once this is done, planners can begin to explore desired system attributes and capabilities. Generally speaking, timeliness, accuracy, completeness, and retrievability are considered of primary importance in the design of a system; user acceptance, usage rates, and costs are major considerations in implementation (180, 218). Because some of the main impediments to successful computer-user interface have been slow computer response time, lengthy and complicated sign-on dialogues, and special computer languages (63), the system should be "user friendly," i.e., easy to use, nontechnical, and speedy. While users will have different expectations or preferences regarding system capabilities (88, 142, 174), the system should generally satisfy the following criteria (48, 216, 229):

1. It must be flexible, allowing the hospital to tailor the system to its particular needs.
2. It must be evolutionary, permitting both gradual implementation and change according to developments in technology or changes in hospital needs.
3. It must be efficient and reliable in data collection, input, retrieval, and presentation.

The following features would further enhance the capability of an HIS. It should be modular (to give the individual functional areas autonomy and responsibility for their own systems), integrated

(to allow the various clinical and administrative functions to communicate), self-justifying (the resulting information itself should provide sufficient motivation for providers to use the system and to make needed changes in their patterns of care), portable (might be "off the shelf," but should not require extensive in-house development or modification), maintenance-independent (not requiring a resident staff of computer professionals), and financially untaxing (public domain vs. proprietary) (48, 216, 229).

Most automated analysis systems are examples of one of three classes of technology (35): (a) manual systems (such as the ECG) that assist in acquiring, storing, using, updating, and transferring patient data; (b) semi-automated systems (resulting from the introduction of a digital computer into the measurement system) that can transmit medical signals directly or indirectly to the processing system, analyze signals instantly, and display results of a variety of output devices; and (c) fully automated systems (such as those used in monitoring post-surgical patients), able to operate without direct human intervention on the basis of programmed decisions that are initiated automatically by certain patient-emitted signals. Fully automated systems are still experimental and exist only in carefully controlled, developmental situations. However, the continued refinement of computer software, miniaturization techniques, and electronic advances suggest that they may be the systems of the not-too-distant future.

There are several basic strategies that may be used in designing an automated hospital information system. Most can be described in terms of a continuum bounded by two design strategies: Methods Improvement, and the IDEALS (Ideal Design of Effective and Logical Systems) concept (72). Methods Improvement aims at identifying changes that can be made in the existing information system. These changes include eliminating unnecessary operations, combining and simplifying operations, or changing their sequence. The resulting system must satisfy design constraints of the hospital, such as the requirement that existing hardware be used. The IDEALS concept aims at a conceptual model for a target information system. It satisfies design objectives but is free of any constraints. Once the ideal system is designed, then environmental and technological limits that prohibit implementation are considered, and the design is modified the minimum amount necessary to make it feasible.

Navy hospitals have essentially been directed to follow the first of these strategies, that is, to make optimal use of existing resources (92). There are, however, more than two points on this strategy continuum, and Goldman and Leonard (72) recommend a middle course exemplified by the component design strategy. This strategy attempts to combine the virtues and avoid the pitfalls of both extremes. In this approach, the designer identifies candidate system components that have proven workable in environments similar to the one under consideration. A model system that meets design objectives (user needs, etc.) is created from a set of these components and is modified as necessary by design constraints. In this way, designers are freed from a myopic focus on the existing system without wasting time and effort in developing system elements.

As an aid to designers interested in component-based HIS design, the Health Services Research Center/Health Care Technology Center of the University of Missouri-Columbia has prepared an Automated Hospital Information System (AHIS) Component Catalog (8). This catalog contains standardized descriptions of costs and performance for each of the commercially available components

discussed. Information describing a large number of hospital sites where HIS components are being used and the total data processing operations at those sites is also included. Search strategies enable the designer or planner to use the catalog in a number of ways. A search may be based on the identification of particular HIS functions, for example, or particular component vendors, or a selected hospital or group of hospitals using automated information systems. The catalog is a source of design ideas as well as documentation of the current level of automated information processing in American hospitals.

It is the designer's job to design the system and advise members of the hospital planning committee; it is not the designer's job to choose the system that will ultimately be purchased and installed. The planning committee should be actively involved in all phases of system selection. One of the most important steps is to visit an operational site of the system being considered. Not one, but several members of the committee should attend this briefing, and team members should make contact with people representing different points of view--counterparts who are actually using the system on a daily basis. A valid evaluation can be made only by asking detailed questions concerning the system's operational routines and/or problems. Marion Ball (10, pp. 30-32) has compiled several lists of such questions, grouped according to the service or area involved. The suggested guidelines for inquiring about general system functions, medical records, laboratory, and pharmacy systems are listed below.

1. <u>General System Functions</u>

Does the system...

(1) Contain general message capability? (enter message into terminal; transmit to all other terminals, selected set, or all but certain terminals)

(2) Contain a file reconstruction program from log and checkpointed files?

(3) Allow for programming for 'catch-up'? (speeding up the internal clock)

(4) Contain priority message output capability? (e.g., send STATS before routine messages)

(5) Allow for automatic routing of messages to alternate stations if destination printer is out of service?

(6) Recall and redisplay or reprint already transmitted messages?

(7) Charge, as part of processing? At optional points? (e.g., order entry, specimen collection, results entry)

(8) Contain a macro-order capability? (e.g., one order generates many - such as Dr. Jones' T & A orders)

(9) Generate a report of doctors' orders expiring in 'X' hours?

(10) Generate documentation for:

- General information or application description manuals?
- Systems flows: general, logic flow charts?
- Program listings, programmers' manuals?
- Operators' manuals (system, terminal operators)?
- File organization and content manual?

(11) Generate file creation and/or file maintenance programs?

(12) Update (add, delete, change) records through terminals?

(13) Have the capability to be used by more than one hospital concurrently? (consider two hospitals, 50 miles apart)

(14) List the files updated in a real-time mode? In a batch mode?

(15) Have easily changed parameters? What are they?

(16) React if entries are made outside expressed options? In what way?

(17) Allow for types of data to be maintained manually? What are they?

(18) Allow for numerous terminals to use the system concurrently? How many?

2. Medical Records

Does the system...

(1) Allow for inquiry into the patient history file for identification and number assignment purposes?

(2) Create diseases and operations indices?

(3) Create audits of reports due (to complete the medical record)?

(4) Create delinquency reports?

(5) Generate utilization review reports?

(6) Control the physical location of the medical record?

3. Laboratory

Does the system...

(1) Time-initiate specimen collection schedules? If so, is summarization by specimen type and contained type available?

(2) Allow entry of confirmation of specimen collection? Allow entry of receipt of specimen at the laboratory?

(3) Time-initiate unreceived specimens report and uncollected specimens?

(4) Edit check the order entry by:

- Checking for duplicate orders?

- Checking for consistency of test and specimen (e.g., AFB with peritoneal fluid)?

(5) Time-initiate preparations for complex laboratory tests, such as BSP?

(6) Assign a specimen number?

(7) On order entry, explode complex tests into component tests?

(8) Have a programming capability for the attachment of automated (analog or digital) laboratory analyzers?

(9) Check quality control of reports?

(10) Enter manual test results:

- For urinalysis, serology, chemistry, hematology, bacteriology with sensitivities, toxicology, etc.?

- Hold results in the system for review by pathologist?

- Allow for immediate transmission of results to the nursing station?

(11) Create a cumulative summary of laboratory results?

- By inquiry at a terminal?

- On patient care summary report?

(12) Provide programs for complex mathematical calculations performed at a terminal?

(13) Create statistical reports?

4. Medications and Pharmacy

Does the system...

(1) Time- and/or demand-initiate medications schedules?

(2) Allow for entry of confirmation of administration?

(3) Generate a follow-up report (reminders, time- or demand-initiated) of unconfirmed administration?

(4) Edit check order entry by:

- Checking duplicate orders?

- Checking inconsistency of parameters (e.g., capsule with I.V. route of administration)?

- Allergy checking?

- Drug-to-drug incompatibility checking?

- Drug-to-laboratory testing incompatibility checking?

- Duration-of-order checking?

- Toxic dosage checking?

(5) Time-initiate schedules for the pharmacist for:

- Unit-dose dispensing?

- Order-duration dispensing?

(6) Automatically update the inventory?

(7) Accumulate dosage of drug by patient?

(8) Provide summary of administrations by patient?

(9) Allow entry by:

- Generic name?

- Trade name?

- Text?

(10) Display or print-out (on request) of the applicability, contraindications, etc., of a medication?

(11) Have a capability for narcotic control?

While this list is not exhaustive, it does provide an excellent overview of issues germane to the selection of an HIS.

Information Networks

A nationwide, American Medical Association-sponsored information network will soon be completed and made available to every subscribing physician who has access to a computer terminal (42). The system will link physicians with four vast databanks of computerized clinical information. These databanks include journal articles, drug evaluations, and listings of medical meetings. Connections will be made via telephone service to the computers of General Telephone Electronics, AMA's partner in the project. The network represents an important advance in electronic information systems for clinical use. After field testing and refinement, it should be as responsive to the needs of a rural general practitioner as to the requirements of a specialist at a university medical center.

The network just described is somewhat like a centralized, remote medical library translated into electronic impulses for instant access in the doctor's office. It does not involve individual patient records--nor should it, given the objectives of the system. An information network for patient-specific or clinic-specific information would be much more difficult to realize on such a large scale, though researchers hope someday to accomplish this objective. On a smaller scale, however, a common databank of patient information is currently available. Multi-hospital operations represent the leading market for such systems.

There are several attributes of a multi-facility health care system that distinguish it from a group of independent hospitals (71). For one thing, multi-facility systems share a mandate to supply comprehensive health care to a defined population of beneficiaries. Another characteristic is the need for such systems to achieve data compatibility among facilities, even though this may be complicated by differing sizes, varied services, and diverse patient groups among facilities. A third characteristic is the need for interfacility communication, including exchange of patient information among the various sites. Because of these characteristics, multi-facility health care systems need an automated information system that is clinically based, uniform, integrated, and cost effective over a wide range of operational settings (71). A shared database represents an expedient way to meet these needs.

There are basically three different types of database configurations available: the centralized system, the hierarchic star network, and the non-hierarchic mesh network. Bakker (9) compared all three on required hardware capacity and cost, staffing requirements, reliability and availability, and the development facilities created, and concluded that the centralized design is best. He found that the total hardware of both star and mesh networks is considerably more expensive than that of the centralized system. He also reported that (a) networks require more staffing of computers, (b) reliability of the information system is best realized with a centralized system, and (c) the centralized design offers superior test facilities. Bakker recommended that the distributed approach be avoided as long as the application could be realized by means of a centralized system.

This recommendation is being followed in two sprawling, federally funded health care organizations. Computer-based information systems are being developed and implemented in both the Indian Health Service and the United States Public Health Service. The Indian Health Service is a widely dispersed, multi-facility, multi-organizational, multi-level health care delivery system comprised of 52 hospitals, 99 full-time health centers, and several hundred health stations, as well as a number of field programs (67). It provides health care to approximately 750,000 American Indians and Alaska Natives. The United States Public Health Service is an aggregation of nine hospitals and 26 free-standing clinics, serving a patient population of approximately 540,000 (71). In both of these large multi-facility examples, a centralized database is the design of choice.

Yet despite this de facto support, the centralized vs. distributed database issue remains controversial. With the rapid improvements in lower cost minicomputers, designers are striving to develop modular systems in which minicomputers are integrated through a communications network link (7, 151). These distributed systems store data elements in multiple interrelated locations and can assume various complex configurations (23). The characteristics of the medical information environment often favor the use of a network of small computers (38) and, therefore, a decentralized system. Another important advantage of distributed computing is the option of having a tailored hardware configuration for each functional area of the network (7, 38, 207). Phased development is also made possible with a modular design (7, 71).

Interestingly, two of the most frequently cited advantages of a distributed system are ones that Bakker presents for the centralized design, namely, hardware economy and reliability (7, 9, 38, 207). In distributed processing, the economy argument is based primarily on the cost advantage of

minicomputer hardware. The reliability argument is supported by the fact that the failure of one processor in a distributed system does not endanger the remainder of the network. However, centralized systems generally have back up systems to guard against computer crashes or environmental disasters (9), and the presumed cost advantages of minicomputers may be offset by increased communications and software development costs (7). Distributed information systems may not yet have a clear advantage over centralized systems, but the current trend among users is decidely in this direction (23, 207).

System integration represents the key issue in the centralized vs. distributed database controversy (7, 191, 207). In a centralized system, data as well as computers are distributed throughout the hospital (or across facilities). Individual, autonomous, tailored component systems, well-suited to the operational needs of particular hospital areas, may be incompatible with respect to hardware, software, and databases. Yet the organization as a whole requires a total information system that is comprehensive, functionally integrated, and readily available for use (191). The decentralized database solution appears to lie with a recently developed technology known as a local area communications network (LACN). The LACN is an intelligent network design capable of connecting together heterogeneous minicomputers serving different user communities (191, 216). This system is currently operational at the University of California, San Francisco Medical Center, where it integrates four stand-alone minicomputers in four different departments (Registration, Medical Records, Laboratory, and Pharmacy) without compromising the autonomy or operations of any area. The architecture can be expanded and reconfigured so that new units may be added without modifying existing units.

Networking, of course, is not limited to a single facility or location. Current development of the Navy Occupational Health Information Monitoring System (NOHIMS), for example, will culminate in a network capable of linking two or more disparate facilities, such as a regional medical center and a shipyard (151). Successful implementation hinges primarily on an LACN-type interface/relay mode that will access the required data from one or more separate data files and perform any data transformation necessary to make all information compatible. Achievement of integrated, multi-facility health information networks will greatly promote interfacility research collaboration. Hospitals are already aware of the potential benefits of sharing information systems, and a few experimental programs are producing positive results (4, 20, 187). Researchers envision a future network of statewide or even nationwide proportions and cite numerous benefits that would accrue from such an aggregated database (6, 39, 98). But expansion in this direction must await certain technical and conceptual advances.

Technical obstacles include poor medical terminology and the absence of reliable patient identification (111). Lack of uniform, standardized terminology is problematic even within a single hospital; the problem on a statewide or national scale would be enormous. Likewise, patient identification is a fundamental technical problem that various identification schemes, e.g., social security number, uniquely numbered patient record, and wrist bands, address but do not completely solve. It has been suggested that fingerprint analysis may represent a viable alternative but is not technically feasible at the present time. Sweden and England assign a logical and unique identifying number to each of their citizens, yet even under these circumstances record-matching

problems occur (1). A third technical problem, that of interfacing and integrating the local databases, is well on the way toward being solved.

As is often the case, the feasibility of a national medical record information system is limited more by problems of a sociopolitical nature than by technology (38, 111). Although the stated purpose of such a network may be clear, the individual citizen may be reluctant. Invasion of personal privacy is the primary conc[illegible]. What control over release of his records will the individual retain? What control exists over possible uses and misuses of the information contained therein? What means will be taken to insure accuracy, protect confidentiality, and limit access to these nationally available medical records? Depersonalization is another issue. The American people seem willing to accept automation and its accompanying depersonalization if it can be shown that service is really improved as a result. But as the interpersonal aspects of medical care continue to demonstrate powerful associations with patient satisfaction and compliance (54, 102, 175), the spectre of becoming a logical, unique number in the nation's medical system may generate considerable resistance.

<u>Database Management</u>

Basically, a database is composed of data and the software used to enter and manipulate the data. All databases require certain well-integrated software subsystems, including: (218, p. 2):

1. File storage systems: software to allocate and manage space for data kept on large computer storage devices, such as disks or tapes.

2. File access methods: software to rapidly access and update data stored on those devices.

3. Data description languages: means to describe data so that users and machines can refer to data elements conveniently and unambiguously.

4. Data manipulation languages: programs to allow the user to retrieve and process data conveniently.

When data are to be accessed by a variety of users, a database management system (DBMS) is needed to protect the reliability, privacy, and integrity of the database (218). This need not be a commercial DBMS, though locally developed programs rarely have all of the protective features that are desirable for a hospital information system. Several distinct types of DBMSs have been developed. Not every type will be available for use with a given computer, but there is usually some choice. The choice of a particular DBMS will influence the structure of the future database, making certain management programs more appropriate for particular applications (e.g., COSTAR for ambulatory medical records, CLINFO for clinical studies). Conversely, the type of database model being used will be a central factor in the selection of a DBMS, since the range of data structures supported in the conceptual model affects all other components of the system.

The best known types of database models are <u>hierarchical</u>, <u>network</u>, and <u>relational</u> (87, 218). The hierarchical model is the most widely used and is related to tree-shaped database implementations, similar to organizational structure diagrams. Network data models permit interconnections that are much more complex than hierarchies but are otherwise similar to hierarchical models. The relational model is derived from the mathematical theory of relations and sets and has as its foundation the entity-relationship model of real world information (229). For example, patient name, identification number, sex, and date of birth is a much-used relation describing various patients. Patient name, laboratory test name, date of test, and result is a typical relation needed by clinicians.

Unlike the other two models, the relational model will support general inquiry capabilities using a language that is simple enough to be learned by nonprogrammers in just a few minutes. This attribute provides health care professionals with direct access to the data. Moreover, the relational approach allows data retrieval to be dependent only on the data items and not on the structure of these items in the database. Users therefore need only be concerned with how the data items relate in reality, regardless of their database definitions. Because of its flexibility, the relational model may be the best approach to data management, especially in ambulatory care (37, 229).

Data capture is largely the physician's task and is typically accomplished with an encounter form. It is therefore noteworthy, though hardly encouraging, that Kuhn and Wiederhold (104) found little evidence of improvements in today's encounter forms, even though it was recognized in 1975 that encounter form design was in need of attention and research. Two problems in particular need to be resolved. One is the necessity for standardization of classification schema and nomenclature; the other concerns the most effective and efficient means of entering the data into the database.

Many coding methods have been developed to capture data for all types of health information (208). Some of the most widely used are the International Classification of Diseases (ICD), Current Medical Terminology (CMT), Current Procedural Terminology (CPT), Diagnostic and Statistical Manual of Mental Disorders (DSMMD), International Classification of Health Problems in Primary Care (ICHPPC, which is based on the eighth revision of ICD), Reasons for Visit Classification (RFVC), and the Systematized Nomenclatures of Pathology (SNOP). Many others are available. No one method has ever suited the needs of all users, and since certain types of care are totally unrelated to others, there is probably no need to have a system that can classify every conceivable component of health care information in one method (208).

However, within the general bounds of particular kinds of care, e.g., outpatient care, standardization is necessary. This necessity is accentuated by the trend toward multi-facility information networks (129, 130, 133, 208). One way to achieve standardization is by fiat. Either the American Hospital Association (AHA) or the federal government could identify an appropriate model and mandate standardization. The AHA, however, believes that the necessary standardization should take place without legislation (208). Voluntarily integrated data systems are more likely to meet diverse local and regional needs than a single mandatory data system.

A classification and coding system for outpatient health problems was developed at The Johns Hopkins Medical Institution and three affiliated institutions. This development was precipitated by a review of eight existing coding schemes (including the ICDA and ICHPPC) which revealed that none was useful for the entire spectrum of applications that was anticipated (186). The resulting Johns Hopkins Ambulatory-care Coding Scheme (JHACS) is a comprehensive and specific coding system for ambulatory care. About 85% of recorded problems are machine-codable, and the cost of coding and operation is considered to be reasonable when the system is incorporated into an ongoing information system. Classifications are assigned to diagnoses, symptoms, well-care services, and treatment procedures. However, outcomes of care cannot be derived from the classifications.

Perhaps the most promising new work to date for a generally applicable, standardized nomenclature-classification scheme is the development of a system called SNOMED (Systematized

Nomenclature of Medicine) (44). The project involved literally hundreds of consultants in medicine, surgery, and computer science from around the world. The final product is a comprehensive, multi-axial nomenclature for the entire health care system. The current edition has seven 'axes' or conceptually clustered coding indexes (Anatomical Topography, Morphology, Etiology, Function, Disease, Procedure, and Occupation), each of which is comprised of appropriate sub-indexes. The system is computer-compatible and has logical, open-ended modules that permit additional axes to be incorporated in the future. Because SNOMED can express all the necessary diagnostic detail of a patient's signs, symptoms, problems, and disease components, as well as document the final diagnosis in the disease classification axis for statistical reporting, it is now possible to develop computer algorithms for the diagnosis of disease. SNOMED has been successfully field tested and represents the most comprehensive medical nomenclature-classification system yet devised.

In addition to the problems associated with standardization, data entry represents a formidable challenge to the data capture process. Weed (210) believes it is most logical to have the physician enter problem statements (for the Problem-Oriented Medical Record) directly into the computer by selecting the appropriate statements from logically grouped displays or menus of alternative problems on a terminal screen. However, menu formats and time required for data entry are viewed as potential problems (233). Rodnick (157) maintains that it is doubtful whether any direct machine-physician interface (type, touch, menu selection, or other) will permit as rapid a recording as a written note or a few sentences on a dictaphone. Wiederhold (218) recommends minimizing changes in the traditional manner of data recording (generally free text or dictation) and simply having clerical personnel transcribe the reports into the computer. Others argue that the two-step process is inefficient and does not address the problem of illegible or incomplete records. Moreover, when textual data are to be used for analyses, they cannot be processed in the form in which they were entered but must be codified in some way. This process is complicated, whether done manually or with software.

A variety of options exist for encoding data. The following list is taken from Wiederhold (218, p. 12), who concludes that the continuing development of fast display technology favors the options which appear later in the list.

1. The encoding can be carried out by clerical personnel (201).

2. Natural language, i.e., English text, may be analyzed and converted by a program that processes the text within the medical context (141, 149).

3. A constrained set of keywords for data values--for example, the list "no, light, moderate, serious"--can be attached to the schema entry for a specific data type. These data values will be converted on data entry to an internal code (219).

4. Where the number of possible data elements for which data are to be collected is large, the name of the data element, e.g., "facial rash," may be encoded in addition to the data value itself (228).

5. Keywords may be checked on a form or selected from a menu presented on a display screen (172). Selection can be accomplished using touch-sensitive screens, lightpens, cursors operated by joysticks or keypads, or by entering on a keyboard a digit which refers to a line off the presented menu.

6. Where the list of keywords is too long for screen presentation, a hierarchical menu selection can be provided, or a subset of the keywords corresponding to a few initial letters can be displayed (128).

7. The forms or menus to be used for data collection may be generated using the schema of the database management system (81).

Database Security

With the growing requirements for protection of privacy, the increasing complexity and use of computerized information processing, and the growing awareness of potential threats to the confidentiality and integrity of electronic databases, security measures are an essential part of database management. Computer security is an umbrella term referring to protection of data against accidental or intentional disclosure, destruction, or modification (30, 171). Security issues are of two basic types: data integrity, involving accuracy, reliability, and completeness of the database, and data confidentiality, involving access to and disclosure of information in the database. Threats can be accidental or intentional, physical or non-physical, issuing from people or natural hazards, and directed at the system, its environment, or its contents (171). Threats are manifold and have to be met by an appropriate set of hardware precautions, software measures, and organizational procedures, such as audit trails (74, 167).

One-hundred percent security is never possible. A set of security measures is needed which can accommodate the errors, omissions, failures, and other vulnerabilities of any given system. Ideally these security measures are based on a risk analysis, which entails systematically postulating threats, estimating their probabilities, and quantifying loss exposures. However, because risk analysis is so difficult and time-consuming, it is seldom performed (30). As an alternative, a number of detailed checklists have been developed to enable an organization to assess its security level (25, 79, 118).

Data integrity. As data collection represents one of the largest costs in any data processing operation, reasonable measures that help insure data accuracy or integrity are both necessary and cost-effective (204). Detailed checks on data quality inevitably involve manual procedures (55). Manual checks can identify omissions and coding errors that computer software will not detect. They can also help to ascertain the accuracy and completeness of computerized checks that a system does have. Complete manual checks, however, are not feasible with large databases. In large databases, sampling is the only alternative for manual procedures, although a sampling strategy is not as effective as the exhaustive checks that computers can perform speedily and accurately. It is recommended that for large databases, the preservation of data integrity be an internal system function, not left solely to the individual applications (58).

Quality assurance methods should be used for every phase of information processing, from patient selection and data collection to data entry and retrieval. Methods can be univariate, such as preventing out-of-range entries, or multivariate, such as preventing illogical relationships (e.g., pregnant males) (77). Many of the specific checks and procedures to insure data integrity are presented below (74, 77, 160, 161, 171):

1. Manual checks of medical records and computer records for coding errors.

2. Compilation of data summaries such as frequency distributions to check for anomalies. Problems (e.g., excessive missing data) are then investigated further to determine the reason and make necessary corrections.

3. Software bounds for edits of constrained data elements, such that the computer will not accept invalid or out-of-bounds data, and any attempts to enter such data will prompt a computer query regarding the accuracy of the data.

4. Use of record locks or subschema locks to prevent simultaneous updating of records in a multi-user environment.

5. Echo-verification checks on the plausibility of data entries, based on user-defined conditions which are formulated in the data description language.

6. Identification of users who are "accident-prone."

7. Use of common diagnostic criteria and manual checks for compliance with data definitions.

8. Relational edits, such that when the entry of a specific value for particular data elements dictates a restricted range of values for related data elements, the computer will prohibit entry of incompatible values or value-based data elements.

9. Specification of times of data collection to ensure temporal consistency among data elements whose values vary with time.

10. Assignment of several employees to operate the computer central processor in order to guard against intentional breaches of security as well as reduce errors due to operator exhaustion.

11. Division of authority, such that no single individual can both authorize program changes and make program changes.

12. Maintenance of backup data at a remote location, along with copies of all programs. In addition, some redundant backup dat should be stored separately, then used as a check whenever the database is changed to be certain that no unintended alterations have occurred.

Despite all these precautions, discrepancies among the data will continue to arise. This is partly due to the imperfectability of the safeguards, or at least their imperfectability within acceptable cost, and operational constraints of an information system. It is also caused by the seemingly inherent unreliability of clinical data. Several investigators have maintained that diagnostic reliability (agreement among physicians) approaching 100% simply cannot be achieved; 60% and 70% levels of agreement are not unusual (17, 107, 161, 208). Therefore, researchers and others who use clinical data need to know the extent to which diagnostic data may be unreliable. Finding information recorded independently by separate individuals (or organizations) at two different times, or in two or more data files, is one key to performing reliability studies (161). Another is to locate inconsistencies between two events when one has certain logical implications for the other (161). A third method is to periodically select a random sample of cases from the databank, delete all data referring to diagnosis, then distribute the unidentified cases to appropriate physicians for review. Results are then examined for indications of diagnostic variability and the usefulness of the collected data for disease state definitions (77). Any redundancy of information in one or several data files may also permit reliability checks. The ultimate aim of such checks is, of course, to reduce unreliability, which ultimately means finding or developing suitable methods to calibrate the human instrument. As Feinstein (57) observed, the problem "is not that clinical data are inherently unscientific, but that clinical investigators have made so few efforts to improve the scientific state of the data" (p. 433).

Data confidentiality. The protection of patient privacy is an area of considerable concern. This concern is particularly acute in automated medical information systems, in which potential access to records is greatly expanded. Because of the wide utilization of medical data for research purposes, careful distinctions must be ma between those situations in which it is necessary to know the identity of the patient or provider, and the majority of cases in which the identifying data can and should be omitted. If proper safeguards exist, the use of unique identifying numbers can serve to link records for research without constituting a breach of confidentiality. Since certain users do need to know the patient's name, full name is routinely entered onto data tapes. One important safeguard, therefore, is to have the name and other identifying information omitted from all routine printouts unless otherwise specified and authorized (73).

In November 1976, the Committee on Standards of the Society for Computer Medicine reached a consensus regarding categories of medical information that are basic to the medical records used by different types of providers and investigators. Each category was then examined to determine the appropriateness of communicating that category of medical information to the various designated users. The users included the primary provider, financial agencies concerned with cost reimbursement, health care planning agencies, clinical researchers and epidemiologists, representatives of quality control programs, medico-legal agents, and employees or schools. Jelovsek, Bolinger, Davis, Long, Oberst, Reid, and Zimmerman (96) have published the results of these discussions in tabular format to be used as guidelines for designers, programmers, and users of computerized medical records. The authors point out that their guidelines apply only to those cases in which the patient gives general, written permission for a medical provider to supply information to an outside user.

Differential access rights have to be determined for all categories of potential users--physicians, nurses, members of the paramedical staff, members of the computer center, researchers, clerks, etc. Once it has been decided exactly who should have access to what information, security measures should be employed to prevent unauthorized entry into the database. This can be accomplished in a number of ways. Each employee who will be using the system is generally given a code or password by which the system determines the degree of access to the information in the master file. Passwords can be accompanied by user identification cards or used in combination with the identification of personal characteristics for added security (10, 74, 167, 171). A hierarchically structured network may contribute to data confidentiality by limiting an individual's access only to the data at his or her hierarchical level (74). If the information is sufficiently sensitive to warrant it, cryptographic systems have been devised to transform data into cryptographic code (74, 167, 171). Encrypting is a rather extreme measure that is seldom used, however, because of the difficulty in using encrypted data, problems in the ciphering of search trees and random access files, and potential omissions in updating long-term medical data as the code changes over time.

Audit trails. System surveillance measures are an integral part of any data security system. Some systems can automatically monitor all inquiries into the system and log those inquiries for future audit (74, 171). Although this does not prevent unauthorized inquiry into the files, it can alert the hospital administration if a breach occurs and provide a record of all inquiries made. Other systems are programmed to simply report attempts to gain unauthorized access (157). In order for such a log to be useful to those investigating a security breach, the time and date, location of the terminal, identity (or pretended identity) of the user, modules and data files accessed (or attempted), duration of operation, and produced output should also be recorded. A properly functioning audit mechanism should allow the specification of certain system events (such as OPEN, LOGON, etc.) to trigger an audit trail (40). In addition to detecting security threats, the effectiveness and operability of the entire system, especially the protection mechanisms, must be continually scrutinized and measured (30). Redundant controls guarding all of the many interfaces in the system are the best insurance against threats to the confidentiality and integrity of the medical database.

Hardware/Software

Three classes of computer systems are presently available: stand-alone systems that function independently and provide the component parts for expanded applications; hybrid computer systems, which draw on isolated, stand-alone systems but are usually directed to administrative rather than clinical use of medical information; and comprehensive, integrated medical information systems that focus communications on the integrity of clinical information (130). To date, the majority of applications in medical computing have been of the second sort. Commercially available systems offer a wide range of choices in terms of the central processing units, terminals, programming languages, and security measures used in their communications networks. Marion Ball (10) has reviewed 15 different commercially available hospital information systems in order to give planners a basis for evaluating their own needs and how those needs might be met.

Regardless of the type of system under consideration, several options exist for acquiring the necessary hardware and software (5). The hospital may either buy or lease the computer, peripheral devices, and programs. It can set up and staff its own computer center, or hire a company to run the center. Two or more hospitals may elect to share a computer and either establish a centralized data processing center or purchase computer services from a service bureau. A hospital may decide to have a systems company custom design their system and programs, especially if existing commercial packages cannot meet the hospital's needs.

It has already been mentioned that the development of minicomputers, especially in distributed processing configurations, constitutes a major advance in computer technology and significantly enhances the availability of automated systems to both large and small medical facilities. There is no precise definition that allows a distinction to be made between a minicomputer and a "regular" computer, but minicomputers typically cost in the range of thousands and tens of thousands of dollars, while standard computers run in the hundred-thousand dollar range and up (5). Kuhn and Wiederhold (104) noted that minicomputers were used for nearly every large AAMRS that they surveyed, and some sites were planning to adapt their systems to a microcomputer.

The microcomputer is rapidly becoming the computer of choice for implementing specific functions in health care settings (89, 166). Now that serious software has been developed for microcomputers, and almost 150 companies, including IBM, are marketing them, they are losing their "toy" image and achieving respectability among data processing professionals. It is now possible for every clinic to have affordable computer power comparable to the largest mainframe computer of just 15 years ago. An important application of microcomputer technology is in the development of "intelligent" terminals that are able to share the computational load of the entire system. Such terminals contain substantial memories (171) and software able to provide for multi-programming in a high-level language (80). As the trend toward computer miniaturization grows, however, a note of caution is in order. Philip Kohlhaaf (185), a computer industry official specializing in static suppression, warns that if integrated circuits become too tiny, they may garble data due to their sensitivity to static electricity.

Three types of software are required for any computer system: applications programs, which are sets of commands that direct the computer in performance of specific jobs; compilers, which are programs that translate instructions and subroutines written in a high-level language (such as

FORTRAN, BASIC, or COBOL) into machine language that is used on a specific computer system; and operating systems, which control the internal operations of a computer, such as moving programs into and out of core memory, setting up files in the storage devices, or detecting program errors (5). Applications programs are normally written in a high-level language that users who are not computer specialists can readily learn to use. Since every computer has its own unique machine language, each model requires a compiler for each language that the computer is to be able to support. Of the many high-level languages in use, the MUMPS language, developed specifically for health care applications, is gaining favor among users of hospital information systems. The major limitations of MUMPS are the scarcity of trained programmers and the relatively small number of computer manufacturers who offer MUMPS compilers (5). (MUMPS code is not compiled but is interpreted as it is executed, thus increasing execution time.)

Austin (5) has assembled a list of 30 different applications packages available to hospitals from at least one of the major sources of hospital software (e.g., computer manufacturers, systems companies, and software companies). An extensive listing of clinical software vendors, including names, addresses, and telephone numbers for the corporate contacts, has been published by the American Medical Association (148). Although these listings provide a central resource to identify and contact software vendors, a comparable listing of systems evaluations is not available.

COSTAR

The Computer Stored Ambulatory Record System (COSTAR) represents a system which is well suited to a variety of outpatient settings (184) and is presently being pilot tested at 26 installations in the United States (60). COSTAR systems are currently operational at the Hays Army Community Hospital, Fort Ord, California (135), and at the USAF Hospital, Pease Air Force Base, New Hampshire (56). Kuhn and Wiederhold (104) report that COSTAR is clearly the leader in commercially available, in-depth medical records systems at this time.

The objective of COSTAR is to provide comprehensive and integrated information processing support for the medical, administrative, and financial needs of an ambulatory practice. It is unique among automated health information systems in the extent to which the medical record can be automated and accessed for daily patient care and quality assurance (100). The Medical Record module represents the core of the information system and provides a large variety of options for recording, manipulating, organizing, and displaying the data (106). Data are collected on preprinted encounter forms designed to fit the needs of a particular practice. The data are entered into the computer via terminals operated by clerical staff, and direct inquiry into the database is possible through all authorized terminals in the practice (e.g., those in the medical record room and in the care areas). Each data element in the patient record is associated with a specific name and a unique code representing the data element. A set of all of these elements constitutes a COSTAR directory (e.g., a directory of diagnostic codes, medication terms, or laboratory test normal values). Content can be modified or extended to suit any particular practice. This feature customizes the system without forfeiting the advantage of a defined vocabulary to use in the collection, organization, and display of information.

There are three different types of output provided by COSTAR: Encounter Report, Flowchart, and Status Report (218). The Encounter Report displays the data collected on a single visit encounter

form (including diagnoses, procedures, medications, and disposition) along with any laboratory test results associated with that encounter. Flowcharts emphasize the temporal course of the disease process or the variation in clinical findings over time. Examples include charts of measurements, immunizations, and developmental milestones. The Status Report serves both as an index to the content of the medical record and as a summary of the most recently collected data.

COSTAR is an active or responsive system in that the processing and display of information are a function of the data content (218). That is, the computer can "understand" the encoded data and tailor output according to the characteristics of the individual patient and the care which has been given. Programs can thus be written to monitor recorded care and to automatically notify the provider whenever a deviation occurs. This is in sharp contrast to the conventional record, which is completely passive, archival, and insensitive to the content or significance of the information.

Barnett, McLatchey, Smith, Morgan, Zielstorff, Shusman, Piggins, Beaman, Barrett, and Colloff (14) reviewed the current status of COSTAR and identified several factors which have either facilitated or inhibited implementation at various sites. Design objectives which make COSTAR an attractive technology are:

1. COSTAR consists of a comprehensive set of relatively independent components which can be implemented in an incremental and modular fashion.

2. The medical structure and content of COSTAR are not prespecified, but are defined by the individual practice through additions or modifications to an extensive directory.

3. The system has a very flexible surface behavior, allowing it to be tailored to the needs of an individual practice without requiring extensive programming.

4. There is active support of COSTAR on the part of both the National Center for Health Services Research and a user group; this provides a community of enlightened users who can share ideas and experiences. (NOTE: NCHSR support ended January 1, 1983.)

Major problems associated with the implementation and use of COSTAR include:

1. A number of programming errors and functional limitations existed in the early versions of COSTAR.

2. The start-up effort required of personnel in the medical practice during the initial months of implementation has been greater than desirable.

3. Because of the complexity of the COSTAR system and the sometimes inadequate documentation, several of the vendors have had considerable difficulty in understanding the system and in providing user support.

4. The cost of the required computer hardware has been greater than anticipated; it has been impossible thus far to implement a dedicated computer system for less than $50,000.

In an independent review of the COSTAR program, Hattwick and his associates (84) found a large number of difficulties relating to hardware, software, and user interface. Hattwick describes some of the modifications and enhancements that have been required for practices to make use of COSTAR. His recommendations for the future include better hardware, more efficient and more user-oriented software, and the establishment of, or access to, a complete supporting organization to deal with problems and provide long-term technical and advisory support for COSTAR users. Despite the problems, his overall appraisal of the system's capabilities and possibilities is nevertheless positive and optimistic.

User Acceptance

Recent research has shown that the human element in computerization is routinely ignored in feasibility and pre-evaluation studies (53), yet no medical record system, no matter how attractive or inexpensive, can survive without the support of the providers who use it. User acceptance or

resistance to the ADP system thus constitutes a key factor in the fate of the automation program. It is one of the only factors that could undermine the entire system in the very first year of its existence (90).

Resistance can assume a variety of forms, from complaints and lowered morale to the withholding of data and mistreatment of hardware. It may be due initially to such things as satisfaction with the status quo, perceived threats to job security or independence, interference with social relationships, or dissatisfaction with the extra effort and general disruption of routine that is caused by ADP implementation (90). After the system is in operation, resistance may stem from unrealized positive expectations, apparent inferiority of the new system's performance compared to that of the old, inconvenience or confusion concerning system operation, or delays in communication and corrective responses (205). COSTAR, for example, uses structured, precoded forms for data collection, but such forms limit freedom of expression, and physicians tend to consider structuring as an infringement. This perception often generates negative feelings and resistance. In order to avoid system failures due to inadequate user preparation and consultation, it is imperative that management develop and employ strategies to minimize the problem of resistance (10, 29, 86, 90, 91, 104, 205).

User involvement and strong, interested leadership represent the primary methods of promoting user acceptance. User involvement requires that those individuals who will be affected by the system be given an opportunity to understand the issues and contribute their knowledge, experience, and judgment. Provider acceptance is greatest when the provider (a) participates in the decision to install the system, (b) is involved in the system's design, and (c) receives adequate training in using the system. Users must be made to feel some degree of ownership of the system. Employee involvement in each step of system specification, design, implementation, testing, training, and evaluation will enhance the correspondence between the new information system and the needs, values, and past experiences of the employees.

In addition to user involvement, implementation success is directly related to the organizational position, leadership strength, and interest level of the individual who directs and controls the effort. This individual should be selected from the highest possible level of the hospital organization. He (she) should be decisive, organized, and enthusiastic. Strong leadership is not incompatible with group participation; both are essential for achieving successful implementation.

There are a number of other strategies that will help overcome res. ance and insure the success of a new ADP system (29, 90, 205). Staff visits to sites where similar systems have been successfully introduced can do much to alleviate fears and uncertainties about the prospective change. Competent coordination and honest communication about the system are vital. Realistic expectations, including the anticipation of some temporary traumas and problems, will foster user acceptance far better than unrealistic expectations that are not met. The quickest route to positive attitudes toward the new system is for results to exceed expectations. Training should take place immediately before it is applied in the real world situation and should be relevant to the jobs that will actually be performed. The benefits of a well-conceived training program include user acceptance as well as user competence and even increased productivity.

Ainsworth (3) states that perhaps the most important factor in generating and sustaining user cooperation lies in scheduling the project. Whenever possible, the new system should be installed during a period of relatively low seasonal workload. A one-step-at-a-time procedure helps to reduce confusion, encourages ongoing staff involvement, and helps to identify problems that could affect future phases of the program. Also, it should be recognized that a system can be developed and implemented in much less time than the ordinary user can adapt to the system. Therefore, a phased implementation is recommended to allow for both adjustment of the staff and resolution of problems that arise during each step (3, 29, 56, 88).

Rosenfield (162) reports that at a number of hospitals where computerized information systems are in operation, clinicians do not want to be involved with the direct use of automated equipment. His initial impression was that this was largely due to inadequate orientation of the users. However, upon further study, Rosenfield became aware that insufficient attention had been paid to the need for an effective but simple technique to permit the prime user to communicate directly with the computer. Human factors engineering is thus a design problem with direct implications for user acceptance. Designers must find ways to express medical information that can be processed by computer and yet be easy to read and write. They must develop means to input large amounts of medical data without input errors. In addition, they must provide simple, user-oriented operations for different types of data processing, such as case retrieval and statistical analysis (94).

Hardware design (e.g., terminals, keyboard layout, information display), software design (e.g., information coding, information formatting, dialogue mode, feedback and error management), and workspace design must all be considered for their impact on human performance. It is quite likely that many basic psychological factors found to be fundamental to good system design in other applications will pertain equally to the design of computer-based systems. The general user considerations present in the specific application of the human-computer dialogue are compatibility, brevity, flexibility, immediate feedback, and operator workload (223). In addition to these attributes, a number of specific cognitive factors also need to be considered. Decision-making rules, information processing habits and biases, cognitive styles, contingency task structure modes (i.e., how people can and do perform in given situations), and decision-making frameworks comprise some of the determinants of information systems performance from the "man" side of the man-machine interface (164).

Costs

Economic considerations are one of the main driving forces behind the proliferation of databases (218). Cost and cost-effectiveness issues are therefore deemed basic to the evaluation of ADP in medicine. This is particularly true in large institutional settings, where costly administrative requirements and funding problems may take precedence over medical goals (35, 86, 120). Cost-effectiveness and cost-benefit analyses are potentially significant aids in the attempt to control health care costs and improve resource allocation. However, difficulties in documenting the developmental and operating costs for many information systems, let alone problems in quantifying their clinical impact, have limited the contributions of cost analysis in this area (86, 140). The impact of computers on the cost effectiveness of clinical medicine is thus open to continuing debate (63, 70).

In the absence of solid research on the costs and benefits of hospital information systems, hospital planners may itemize expected costs and examine some of the actual costs and benefits incurre ™ similar hospitals with operational information systems. The Automated Hospital Information System (AHIS) Component Catalog (8) provides a helpful cost guideline. In addition to outlining the information systems in use in American hospitals, the Catalog includes the total expense of each site's system and a graphic display of the portion of the hospital's resources that are devoted to data processing operations. The recently published "how-to" manual, Evaluating Automated Hospital Information Systems (115), is helpful in evaluating the performance of an information system after it is installed. This manual provides step-by-step instructions for performing a self-guided, in-house evaluation of both economic and service impacts of an AHIS.

System costs include the price of hardware, software, other needed equipment, the monthly charge paid to a service bureau, if one is used, and licensing fees for software (5). Leasing eliminates the large capital outlay required for a purchase and protects the organization from the danger of system obsolescence. In the long run, however, purchase is generally the most cost-effective method of acquiring a system (208). There are also a variety of one-time costs associated with the installation of a new system (5). Shipping and installation charges, purchase of operating manuals, travel expenses for the installation team, environmental renovation (e.g., air conditioning, raised floor, new furnishings), and supplies (e.g., disks, tapes, and microfiche readers) are some of the expenses that should be anticipated. Operating costs include forms, supplies, utilities, salaries, and maintenance contracts. Back-up systems to insure data security represent yet another anticipated expense. The back-up system can be either electronic or manual but should be developed before the new system is installed.

The relatively high cost of data entry is also a major concern (118, 218). Martin (118) found that the overwhelming majority of direct costs (88%) were involved with data acquisition and preparation rather than report generation. When data are collected, there are the costs of actual collection, transcription into some processable form, and entry into the computer database. Obviously, data that cost more to collect than they are worth should be avoided, but the utility of a given data element is hard to predict. This utility depends on its potential value, the completeness of the patient's record, and the probability of the patient returning to the clinic for follow-up. Because of these contingencies, ambulatory data are generally more expensive to collect than inpatient data. Also, because the average bill for a hospitalized patient is many times greater than the average bill for an ambulatory patient, the cost/income ratio for a given piece of information is higher for outpatient data (129).

Costs vary according to the setting. The more innovative or extensive a system, the greater the cost of development and programming. Rodnick (157) reports that of the 17 AAMRS sites that he and his colleagues visited, only four were financially self-sufficient. Friedman and Gustafson (63) surveyed 32 published projects involving computer applications to medical problems. Follow-up questionnaires to the principal authors of these publications revealed that for 51% of the projects reviewed, the work had either been stalled or abandoned. Over 41% of the projects were unfunded by the time of the follow-up survey, and only 18% were funded out of direct patient fees or hospital funds. In almost every case in which the project had been abandoned, the rationale was that the

project had never become cost-effective. When the external research funding expired, the hospital declined to assume the funding.

In general, clear-cut financial savings accrue only from support of billing and accounting functions (120, 157). More indirect service benefits can be justified in terms of cost savings, but every effort must be made to demonstrate that the benefits of a particular computer system outweigh the obvious costs in order to justify purchase and operation of a good system (24, 231).

Due to the fact that the health care industry is service-oriented rather than product-oriented, it is extremely difficult to obtain precise measurements of the benefits of an ADP system in health care delivery. However, Schmitz (171) suggests several examples of quantifiable patient care parameters that could serve as evaluation criteria. These criteria include an increase or decrease in the number of contaminated tests, the number of incorrect requisitions, the amount of time it takes for an item to arrive at a nursing station after a requisition has been sent, and the amount of time it takes for patients to receive some treatment following their admission.

Simborg and Whiting-O'Keefe (180) describe a new evaluation methodology that is currently being developed. This method utilizes the physician's ability to predict patient outcome events as a measure of the quality of the information system. The development rationale stems from information theory, which defines information as the removal of uncertainty from a system. By extension, the better the information, the better one's ability to predict outcomes. Conversely, better predictions mean better information and a better information system. Although the feasibility of the methodology has been demonstrated, a number of issues must be addressed before the validity, sensitivity, practicality, and ultimate usefulness of the method can be confirmed.

The good news. Martin (118) describes a computerized information system in a 550-bed teaching hospital. Cost-benefit evaluation demonstrated that the system was potentially cost-effective in its application to medical quality/utilization review. For example, because the demonstration hospital was already participating in the Professional Activity Study of the Commission on Professional and Hospital Activities, the marginal cost of obtaining fundamental information such as patient age, diagnostic and operative codes, and admission and discharge dates was only slightly above $.01 per patient. This figure is far less than the cost of abstracting, coding, and keypunching the same data with a noncomputerized system. Martin concluded that full cost savings could be realized if the system were implemented in a number of hospitals, with only minor modifications, in order to spread the costs of development over several facilities.

Margolis, Alterescu, Friedman, and Baker (116) have described and endorsed a relatively simple Medical Information Management System (MIMS) in which an automated, optically scanned (Op-Scan) data entry system was combined with a generalized, interactive storage and retrieval system. The user-friendly Op-Scan-MIMS operates in a time-share system, requires minimal hardware and technical skills, utilizes user-generated programs, and has been shown to be cost-effective. Cost of the system is about $2.00 per medical record, a figure which should become even more attractive as the cost of manual data entry continues to climb.

At El Camino Hospital, work sampling studies showed that clerical activities consumed 18% of nurses' time prior to implementation of a hospital information system (66). Of the potential savings estimated for the Technicon Medical Information System, 95% represented labor benefits,

mostly in nursing activities. Evaluation of the economic impact of the system, therefore, concentrated on models of time savings and labor reductions. Over the 4-year period during which the study was conducted, the total net system cost benefits, after deducting for system costs, ranged from -$17,724 to +$98,714 per month. According to the Gall report (66), a more realistic but still conservative estimate for this project is that net cost benefits lay between $30,000 and $50,000 per month.

One of the most controversial aspects of cost analysis of automated record systems is estimating the comparable costs of a manual record system. There have been few quantitative studies delineating exactly what functions and how much personnel support should be included in such estimates, and little quantitative data about the cost of an equivalent manual administrative support system (13). When the Harvard Community Health Plan (HCHP) and its collaborating facility, the Laboratory of Computer Science of the Massachusetts General Hospital, undertook a general cost evaluation of their COSTAR system, they used estimates of an equivalent manual system that were comparable with, or less than, cost estimates from similar health care facilities. COSTAR costs included all hardware and terminals, all communication costs, all operational and programming support staff, and all HCHP staff involved in the medical record and administrative information processing activity. In 1976, their estimates of operational costs in terms of cost per member per year at a population of 40,000 were: Manual Record System--$14.00, COSTAR System--$12.50 (13).

The bad news. The North County Health Services (NCHS) project in San Marcos, California, began installation of a COSTAR system in August 1978 (61). NCHS is a complex of five clinics providing care to some 54,700 patients annually. Prior to the installation of COSTAR V, the project utilized a manual medical record system and operated a batch encounter/billing system which contained basic diagnoses, procedures, medications, and supply data. NCHS hoped to use the COSTAR computer system to eliminate several major shortcomings within their organization. Initial results suggested that system performance was adequate, in that the major system modules were 'bug' free, the software worked as specified and did not cause system crashes, there were few data errors, and current needs were being met. However, high costs and a multitude of development and implementation problems have tarnished the effort.

Not surprisingly, COSTAR V's costs were greater than the preceding system's costs. Total annual costs for the automated system, based on amortization of $161,000 in hardware purchases, were $128,100--almost 60% higher than the cost of the previous system (61, 181). Developers point out that at NCHS, a number of site-specific factors have tended to exacerbate the system's costs and limit potential cost savings. Nevertheless, a comparison of costs at two COSTAR sites (NCHS and a Medical Health Group in Baltimore, Maryland) shows them to be very similar (61, 181).

The NCHS system required more hardware and data entry time than anticipated. Entry of registration data was generally efficient, but encounter form data took an average of 6 minutes, 40 seconds for clerks to enter. Requirements for free text data have slowed data entry time and have placed excessive demands on disk storage. An additional $90,000 of hardware was ordered to improve processing and expand disk capacity. The amortized hardware costs, annual hardware maintenance costs, and personnel salaries were higher than planned, and it became apparent that the system's potential actual cash savings, originally estimated at $10,000 per year, would be far less than the system's yearly operational costs.

There are other examples of cost problems with HIS systems. At the U.S. Naval Air Station Dispensary, Brunswick, Maine, the computerized Problem-Oriented Medical Record was determined to equal or surpass a paper medical record in several respects. However, the average cost of the manual record system was approximately $1.98 per patient visit, while the computerized records averaged $6.13 per patient visit (170).[1] Of 30 selected sites using automated medical records in 1974, Henley (86) reported that only one showed actual cost savings that exceeded the cost of the computerized system. In 1975, Wiederhold et al. (219) noted that attempts to store large amounts of data had not demonstrated cost-effectiveness, and that large systems were seemingly interrupting clinical routines without providing clinicians with usable information in return. Based on a survey of automated ambulatory records, Rodnick and Wiederhold (158) concluded that problems of cost, data entry, and data storage seemed to outweigh the benefits for most practices. In a subsequent report, Kuhn and Wiederhold (104) concluded that there is little evidence that benefits justify costs for the larger automated ambulatory medical record systems.

At the 1981 Symposium on Computer Applications in Medical Care, Ian Bush (32) stated flatly that "conventional automated hospital information systems are still excessively expensive and of very doubtful cost-effectiveness" (p. 5). He went on to criticize those who accept these costs, projected to run 4-7% of total hospital operating costs for a typical 'total' HIS, in the face of no convincing proof that any cost savings at all will accrue from HIS use. He termed estimates of $2.00-$6.00 per patient day "depressing," and referred to automated hospital information systems as "dinosaurs in the land of computers." Conceding enormous uncertainties in figures quoted on both sides, Bush nevertheless believes that all users' ADP costs are seriously underestimated in the available literature. White (215) suggests that a rough rule of thumb would be to spend about 1% of the total annual health expenditures on information. This is approximately what the Navy Medical Department now spends on automated information systems, although some experts have advised that 10% of the total budget is not excessively high (190).

To summarize, conclusive cost-effectiveness or cost-benefit analyses have not been performed. Evidence on both sides is largely observational, and in the absence of further computational details the issue remains equivocal. Rogers, Waring, and Watson (159), for example, identified some of the hidden complexities of cost analysis. Their investigations produced two results with diametrically opposed implications for health care costs. Length of hospitalization stay was found to decrease considerably among patients for whom computerized medical record summaries were available to providers. This suggested a possible savings in overall health care costs. On the other hand, laboratory tests were given more frequently to summarized patients than to nonsummarized patients, which represents an increase in health care costs.

Vickers (204) points out that while hardware and disk storage costs have been in a steep decline, labor has increased. This increase indicates that hospitals should use more computer hardware if it will save labor or make labor more effective and efficient. Banta (12) notes that

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[1] It must be emphasized that all of these figures are merely estimates of system costs, based on certain variable conditions and do not on others. For example, researchers involved with the Brunswick system estimated that with outright purchase of appropriate hardware, as opposed to contracted computer services and rented terminals, the cost figure could be reduced to $1.85 per visit. This revised estimate would represent a slight savings over the paper records.

capital-intensive technologies may actually contribute less to high health care costs than do individual, low-cost items that are used in great quantity.

Thus, the various costs and cost savings associated with computerization have to be examined in light of one another in order to determine what net costs or savings might be. In most instances, an automated information system is not going to reduce costs immediately. In fact, it will probably cause an initial increase in costs. Kammeier (98) recommends buying only the system which is presently needed and cost-justified but which is capable of expansion to meet normal growth needs for the next five years. Cost justification should not be limited to immediate circumstances, but should weight long-range benefits, both tangible and intangible, against long-range costs.

SUMMARY AND CONCLUSIONS

Information Needs Analysis

In the midst of an unprecedented data explosion, many organizations, including the health care industry, have come to regard information as the "fourth resource," equal in importance to money, materials, and personnel. The tremendous volume and complexity of the data, coupled with increasing pressures for accountability, are literally forcing hospitals into the use of computerized information systems. Unfortunately, many hospitals have adopted automated systems without sufficient forethought, assessment of needs, or systems evaluation.

In order to be useful to health care practitioners and managers, data must be captured and aggregated in accordance with the actual needs of specific users. Needs must be established on a facility-by-facility basis through a detailed analysis of each department's objectives, resources, patterns of information flow, and current information system. In general, health care providers require detailed information about the individual patient and his present medical condition, while clinical researchers need longitudinal data and population statistics. Because the medical record is the main vehicle for capturing and organizing a clinical database, both clinicians and researchers share the need for complete, accurate, organized, legible, and accessible medical records.

Medical Records

Computerized medical records are contributing significantly to the solution of three major shortcomings in conventional data collection. One of these shortcomings is the inadequate representation of temporal relationships among various clinical events. Time-oriented records and flow-chart outputs are being developed to enable clinicians to track the status and evolution of disease and treatment processes (64, 179). The time-oriented record is especially useful for managing patients with chronic disorders.

The user's inability to integrate the many discrete facts contained in the medical record represents a second problem addressed by automation. Frequency counts, which characterize the manual limits of large-scale aggregation, have very little clinical, management, or research utility. Information in an automated system, on the other hand, can be retrieved, integrated, and analyzed to meet a variety of user needs. The Problem-Oriented Medical Record is an important example of a computer-generated patient profile, which integrates related pieces of information

pertinent to an individual patient, his problems, and his treatment. Pharmacy and laboratory programs are also contributing to meaningful data synthesis by combining general, population-based medical knowledge with individual patient treatment data to warn physicians of potential drug-drug or drug-lab interactions.

A third problem with most manual medical records is the need for more complete and more detailed information. Increased demand for more detailed medical record information has been precipitated by a number of factors. Quality review, for example, has become more demanding. Accreditation procedures, legal conventions, federal regulations, and resource allocation decisions often involve very specific questions requiring very specific, documented answers. In addition, there is an increasing research and clinical emphasis on subtler dimensions of health and disease. Therefore, new indicators such as functional status and symptom severity need to be included in the medical record. Other clinical considerations include the increase in patient load, the concomitant decrease in the amount of time spent with an individual patient, and the fractionalization of health care due largely to contemporary specialization of services. Finally, the automation of medical records can contribute to the process of standardization.

In order to increase the level of standardization some medical software programs require the input of all necessary information before the user can move to the next item on a record (66). In addition, some newly developed coding schemes permit great specificity in recording symptoms and diagnoses (44, 186). Computerized data storage and retrieval capacity enables users to collect large amounts of data without the storage, organization, and availability problems inherent in manual records. Standardized encounter forms, such as optically scanned checklists or computer-displayed menus, potentially can reduce the amount of writing a physician has to do and improve the quality of the data.

Quality Assurance

Automation can make a special contribution to clinical quality assurance. Computers are able to monitor care as it is being provided, detect deficiencies, and alert providers via automatic rapid feedback so that necessary corrections can be made. Computers have also been employed to supply physicians with reminders of needed procedures (e.g., medications, immunizations, or routine check-ups), enhance prognostic accuracy of physicians (47), and assist in clinical decision-making.

Automated records, because they are more complete, accurate, and organized than conventional records, can improve retrospective quality assessment as well. This improvement is particularly salient in ambulatory care, where special problems exist for both record-keeping and quality review. In ambulatory care, standard assessment measures of process and outcome do not correspond well with actual clinical situations. Outpatient-specific quality review methods are very much needed, but their development is contingent on the availability of sound patient records. A hospital information system potentially can provide such records.

Design and Implementation

The actual design of an information system calls for an intensely cooperative effort between potential users, who will contribute ideas on system requirements and the realities of daily operations, and technical personnel skilled in analysis, design, and hardware/software functioning. The following recommendations are generally supported in the literature:

Minicomputers have been used for several years as independent processors for various functional applications in hospitals. They cost much less than mainframes and yet provide substantial processing, storage, and memory capacity. Rapid improvement in minicomputer hardware and software makes the mini an attractive option for a total hospital information system. While continued miniaturization promises computational power in even smaller packages, we may be reaching a limit on miniaturization due to such problems as the vulnerability of microchips and microcircuits to static electricity. Instead, future developmental efforts will probably focus on improving computational speed and mass storage capacity.

A modular, distributed database is preferable to a centralized design. Efficiency, flexibility, reliability, phased development, and economy are cited in support of distributed databases, although their advantage over centralized systems is not uncontested. Although data integration remains a problem in a distributed database, recent technology, such as the local area communications network (LACN), should resolve this problem and facilitate the construction of hospitalwide, regional, or even national data networks. As is often the case, such developments are hampered by both technical and sociopolitical problems.

COSTAR (Computer Stored Ambulatory Record) leads the field in commercially available, in-depth medical records systems at this time. It is especially pertinent to the Navy's interest in an ambulatory record system. COSTAR's flexibility and sophisticated capabilities are impressive, but its high costs and history of implementation problems must be considered.

Data security assumes new dimensions with the adoption of a computerized information system. An internal database management system (DBMS) is recommended to protect the confidentiality and integrity of the data base and to provide audit trails.

User resistance can undermine even the most powerful, attractive, and economical automated information system. User involvement from the very beginning, and strong, interested leadership are the two keys to user acceptance. User participation in the design of the system will also help to insure that human factors are given adequate consideration. Hardware, software, and workspace designs all impact on human performance and should be built to be user-friendly.

Costs

There is no denying that computerization costs money--$500,000 to $2,000,000 or more per year, depending on the size of the hospital and scope of the system (216). Despite numerous examples of cost-effective systems and net cost savings, an equal or greater number of cost-benefit failures indicate that most systems are still excessively expensive and of uncertain cost-effectiveness. The complexities of cost-benefit analysis in health care, and the dearth of methodologies for performing such analysis, may partly account for the lack of more favorable evaluations.

Users need to become more discriminating consumers. Some tasks should not be automated, as they can be done much better manually. Others can be accomplished more efficiently and inexpensively with a batch system rather than an on-line system (171). In still other tasks, direct input and retrieval of data is less expensive than using an intermediary such as a clerk. This is particularly true in ambulatory care because of its tremendous volume of patient contacts (68). All other factors being equal, labor-intensive systems will tend to cost more than machine-intensive systems (199, 204). In general, packaged systems are more economical than custom designed systems.

However, procurement regulations that limit facilities to competitively procured off-the-shelf systems can actually increase costs because of the need for expensive modifications, delays, or both (17). It is generally more efficient to specify products known to satisfy a particular hospital's requirements.

Future Directions

There is a growing movement among both epidemiologists and medical practitioners to consider health and illness in the context of the physical, social, and psychological factors operant in the human host and his/her environment (214). This integrative orientation requires a shift away from traditional vital and morbidity statistics and toward subjective complaints, symptoms, and personal adaptation. The advent of this ecological perspective may signal an important movement within establishment medicine toward a broader view of health and preventive medical care.

Patient education represents a fundamental aspect of preventive medicine. The Navy Surgeon General has stressed consumer health education as an important means of reducing health care demand (45). Computers are already being successfully employed by patients for their own education, evaluation, and counseling (182, 189, 202). Even children are learning to run programs that are proving very successful in nutrition education. Although researchers are only beginning to explore the potentials of computerized information systems for patient education and preventive care, such applications hold great promise for improved health care and cost containment in the health care industry.

The application of computers in health care systems usually takes two forms. One is to perform tasks that were formerly done by people: the other is to do jobs that were not feasible by manual methods (199). Friedman and Gustafson (63) believe that the generally disappointing impact of computer technology on medicine thus far may be due to the fact that most automated systems do little more than duplicate the efforts of the individual physician:

> In mathematics, physics, banking, space exploration, etc., the computer routinely is called upon to perform tasks that all mankind working 24 hours a day from creation could not begin to duplicate, but in medicine our measure of success is diagnostic accuracy approaching a skilled clinician, ECG analysis which is substantially correct, or historical data acquisition which saves the physician five minutes per patient (63, p. 200).

More imaginative and ambitious computer applications in the future would help to generate increased enthusiasm among physicians (107).

In 1977, the Congressional Board of the Office of Technology Assessment undertook an impartial analysis of medical information systems for the purpose of recommending policy alternatives for the federal government (138). Their recommendations took the form of eight alternatives (pp. 68-73) which are summarized briefly below:

1 Continue current research and development policies and allow dissemination of medical information systems to be determined by the open marketplace. (This presumes that the most beneficial systems would fail to attract buyers and would consequently disappear from the market. The disadvantage of this approach is that the administrative functions, which are the most marketable capabilities, would probably tend to predominate at the expense of further research and development of more patient-oriented functions).

2. Establish a central clearinghouse to coordinate developmental projects and provide information to the public about medical information systems.

3. Provide funding for evaluation of medical information systems in a number of different medical care facilities and locations to determine their effectiveness in terms of relative benefits and costs.

4. Ensure the availability of medical information systems with specified capabilities and applications by contracting for their development.

5. Provide incentives for medical care facilities to adopt medical information systems that improve the quality of patient care and support research and planning. Two possible mechanisms could be employed: regulatory authority over capital expenditures and direct subsidy.

6. Charge a central organization with authority for developing, validating, and maintaining the content of medical knowledge within medical information systems. (Without such controls, therapies, drugs, or tests of unproven efficacy could be incorporated as guidelines for physicians in computer programs.)

7. Develop standardized medical databases, including nomenclature, terms, definitions, classifications, and codes for use in medical information systems.

8. Establish guidelines for precise standards to protect confidentiality of patient data within an institution and release of identified data to third parties.

Although these eight proposals were directed to the federal government in its role as a regulatory agency for the nation's health care industry, they have immediate applicability to policy-making within the Navy Medical Department. The important points for action highlighted in this congressional report include (a) development of clinically oriented information systems to improve and monitor the quality of medical care, and to facilitate research and planning that will benefit the patient and the health care system as a whole, rather than the individual institution (b) dissemination of information about medical care systems to increase public awareness, guide administrators in system purchases, and encourage adoption of medical information systems; and (c) regulation and standardization of the content, form, and security of medical databases. These issues remain priorities in both the civilian and the military health care sectors.

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Comprehensive, high quality health care requires that providers and managers relate all relevant medical knowledge to the needs of individuals in the broadest possible context and in the most coordinated manner possible. Computerized information systems afford powerful means for meeting medical information processing needs. The present report is designed to focus attention of both clinicians and researchers on the salient issues involved in the design and use of an automated medical information system. The literature describing

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the current state of the art of computer applications in medicine is reviewed, with special emphasis given to (a) clinical (as opposed to administrative) applications of health care systems, (b) assessment of information needs and research issues, and (c) design and implementation issues, including methods of data capture, database security, and costs. The report concludes with a brief examination of future directions and policy recommendations for medical information systems.